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# Does increased peri-operative communication improve patient satisfaction after total joint arthroplasty?

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# Does increased peri-operative communication improve patient satisfaction after Total Joint Arthroplasty?




**Dr PI Ntombela**

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine.

Johannesburg, 2022

# Declaration

I Philani Ian Ntombela declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



(Signature of candidate)

20th day of June 2022 in Bryanston

# Dedication

This work is dedicated to the memory of my father SJ Ntombela (1946 – 2020) and my dear friend Dr SK Mkize (1978 – 2017). To my loving and immensely supportive wife Lehlohonolo Ntombela and my 2 beautiful children Enzokuhle and Zobuhle Ntombela, thank you dearly.

# Acknowledgements

I would like to thank my supervisors Dr S. Ndou and Prof M.T. Ramokgopa for their guidance and seeing this work to completion. Also, to my co-supervisors Dr K. Sikhauli and Dr L. Mokete, thank you.

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Thank you to the chief executive officer (CEO) of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) for granting me the permission to conduct this research.

Lastly, I would like to thank Drs T. Hlapolosa, A. Whitehead, E. Osei and H. Aftab for helping with recruitment and data collection in this project.

# Abstract

**Background:** Total joint arthroplasty (TJA) is a very successful procedure. It is reported with relatively high satisfaction rates. One of the pillars in improving patient satisfaction is strengthened communication between surgeons and patients. Technology has made this easier and convenient. The aim of this trial was to determine whether peri-operative cell phone massaging patients undergoing Total Joint Arthroplasty (TJA) improved the satisfaction rate.

**Methods:** We conducted a randomised controlled trial (RCT) of 90 patients and were left with 80 patients at final analysis, 40 participants in each group. The intervention group received short message services (SMSs) in the peri-operative period (day before surgery up to 6 weeks post-operatively) and were compared to the control group which followed the traditional routine. The primary outcome was the satisfaction rate evaluated using a questionnaire. Secondary outcome was functional improvement evaluated using the Harris hip score (HHS) and the Oxford knee score (OKS). Differences between the groups were evaluated using the Pearson's chi-squared test. An independent sample t-test used to analyse continuous variables

**Results:** In the study group, 57.5% were satisfied, 22.5% very satisfied, 12.5% indifferent and 7.5% were dissatisfied *versus* the control group's 77.5% satisfied, 17.5% indifferent and 5% dissatisfied. Asked if they would recommend TJA at CMJAH to their family/friends 80% answered yes, 12.5% unlikely and 7.5% were indifferent in the control group. In the study group 57.5 % answered yes, 20% highly recommend it, 15% were indifferent and 7.5% unlikely. There was no statistically significant difference in pre-operative HHS i.e., *p*-value = 0.07 and post-operative HHS i.e., *p*-value = 0.61 between the groups. There was statistical significance in pre-operative OKS between the two groups i.e., *p*-value = 0.00000032 and for post-operative OKS i.e., *p*-value = 0.00086.

**Conclusion:** The satisfaction rate of patients receiving SMSs is equivalent and comparable to that of patients using traditional forms of communication. The quality of the satisfaction is superior for SMS patients. Patients receiving peri-operative SMSs while undergoing TKA do functionally better. Peri-operative SMSs are beneficial for patients undergoing TJA.

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# Nomenclature

**Apps**……Applications

**BMI**……Body Mass Index

**CEO**……Chief Executive Officer

**CONSORT**……. Consolidated Standards of Reporting Trials

**CMJAH**……. Charlotte Maxeke Johannesburg Academic Hospital

**HHS**……. Harris Hip score

**HREC**…….Human Research Ethics Committee

**IBM SPSS**……International Business Machine Statistical Products and Service Solutions

**IPA**……Interpretative Phenomenological Analysis

**NOF**……Neck of femur fracture

**OKS**……Oxford knee score

**PI**……. Principal Investigator

**POPIA**……. Protection Of Personal Information Act

**PPI**……. Public and Patient Involvement

**PROMs**……Patient Reported Outcome Measures

**RCT**……. Randomised Controlled Trial

**ROM**……Range of motion

**SA**……South Africa

**SMS**……. Short messages service

**THA**……. Total Hip Arthroplasty

**TJA**……Total Joint Arthroplasty

**TKA**……. Total Knee Arthroplasty

**USA**……. United States of America

**WITS**……. University of the Witwatersrand

# CHAPTER 1

# INTRODUCTION AND LITERATURE REVIEW

## 1.1 Background and Literature review

Over 700 000 Total Joint Arthroplasties (TJAs) were performed in the United States of America (USA) in 2014 and these numbers are projected to increase in the coming decades (1). More than 63 000 hip replacements and 75 000 knee replacements were performed in Canada in 2019 – 2020 (2). An increase of 2.4% for hips and a decrease of 0.4% for knees compared with the previous year. The relatively stable volumes are likely due to the beginning of the pandemic in March 2020 (2).

Eighty three percent (83%) of the studies report more than 80% satisfaction rate for Total Knee Arthroplasty (TKA) and up to 90% satisfaction rate for Total Hip Arthroplasty (THA) in separate studies (1). I believe that while these may seem like reasonable numbers, they are relatively low. It is my opinion that one of the pillars in improving patient satisfaction is a strengthened communication system between surgeons and their patients.

With the growing use of cell phones, communication has been improved not only for the general population but also between doctors and their patients. As communication is the cornerstone between patients and doctors, there is an opportunity to explore patient satisfaction with the use of cell phones as a tool to keep patients informed.

In South Africa (SA), a country with 11 official languages, communication between doctors and their patients remains particularly imperative but also difficult. The protection of personal information act (POPIA) came into effect in July 2020. Part of its aim is to guide lawful processing of personal information (3). This was very important when designing the content of

the short text messages to be sent to patients. As a result, the messages did not pertain to personal or confidential information.

Day et al. in their 2017 paper reported that 87% of the participants felt that messages helped them be better prepared for surgery and 100% were better informed (4). Use of such a tool is not only aimed at improving patient satisfaction, but also improves access to care and health care facility ratings. While the use of cell phone messaging is hypothesised to improve patient-satisfaction provided the patients can operate one, it does not take away the value of interpersonal interaction between patients and staff. In a study by Gwam et al., the authors explored what factors influenced patients with clinical depression in their rating of their hospital stay following TJA. The only factor found to be statistically significant was the patients' communication with the nursing staff (5).

The ethical dilemma attached to communicating confidential patient information *via* messages cannot be ignored but still does not preclude this initiative. Over 40 000 digital mobile applications focus on healthcare but still do not cater for both doctor and patient interactions (6). Effective communication between physicians and patients lays the foundation for an optimal patient experience with a high satisfaction rate (74.2%) and patients reporting an improved hospital experience when using digital mobile technology to communicate with their surgeon peri-operatively (6).

Face to face interaction between in-patients and treating surgeons on a constant basis is near impossible. Furthermore, as it has been shown that even with occasional lapses in communication, there is a decrease in "word-of-mouth" recommendation by patients to their friends and family. Thus, the use of cell phone messaging may potentially negate this problem (6). Implementing the use of cell phone messaging as a tool for doctors to communicate with their patients on a routine basis also has its challenges. Bishop et al. reported that some

physicians felt this was more work for them, and the lack of payment for such services was cited as a barrier (7). Despite this, the advantages gained from using cell phones to communicate with patients outweighed the disadvantages.

In a multilingual country such as SA, standardised messages may prove to be a challenge. Although the overall use of cell phones is increasing, TJA patients are generally of the older age group and may not be technologically familiar with the use of smartphones. While the study question was limited to the peri-operative period of orthopaedic patients, one study has extended the use of cell phones to the long-term care of patients in multiple other specialties and obtained good results (6).

Angelo et al. showed the incentive for optimising patient satisfaction is that satisfied patients will return to the clinic from which they received quality care, as well as refer their friends and family (8). Since the early 1990's there has been a drive by healthcare industries towards continuous quality improvement and this is used by healthcare managers to improve patient-centred care (9). Due to the increasingly competitive market of healthcare industries, patient satisfaction becomes particularly important (9). Efforts looking into improving this are worth exploring which adds relevance to the proposed study. Modifiable factors such as communication behaviour by physicians play a statistically significant role when it comes to patient satisfaction as opposed to non-modifiable factors such as age, gender, and education level (9,10). This clearly demonstrates an opportunity to improve on the question of communication.

One of the seven attributes of patient-centred care mentioned in a paper by Davis et al., is patient engagement in care, adding more emphasis to communication between surgeons and the patients they operate on (11). This paper also acknowledges the use of computer-based guidance and communication systems to improve patient satisfaction (11). These are relatively

more sophisticated modalities as opposed to what the aim of our study was set out to investigate however, this is still applicable.

In a study conducted by Al-Abri and Al-Balushi, the authors reviewed the available literature on patient satisfaction. While there was no consensus on the definition of patient satisfaction, factors contributing to it could be identified (9). The first important factor when it comes to improving patient satisfaction is courtesy and respect from healthcare providers (9). Communication and providing an explanation to patients were the second most important factors (9). Only 33% of physicians were rated as excellent for their communication behaviour and as low as 16% communicating *via* email with their patients. This represents a missed opportunity to improve on this area (9,11).

Validity of the tools used to assess patient satisfaction has little impact. Most institutions utilise internally developed instruments for outpatient satisfaction and choose to use private vendor's instruments for inpatient satisfaction (9). Of concern is that many of these patient satisfaction surveys are still not being used systematically to develop improvement initiatives (9). Stewart et al. found in their study that patient-initiated consultation meant an improved understanding of their complaints by their physicians (12). This could be extended to patients being allowed to reply to the standardised messages or even initiate them. This of course would be a task for future projects and not of the current study.

Stretching the use of electronic/digital modalities for doctors to communicate with their patients was also examined in a study by Vardanian et al. The authors investigated the use of social media in medical practice by plastic surgeons and reported that 50.4% of them used social media in their medical practice (13). Furthermore 49.0% of the surgeons felt it provided them with a platform for education, 52.1% used it as a marketing/advertising tool, while 56.7% felt that incorporating social media in their medical practice was inevitable (13). Only 1.5% of

surgeons reported a negative impact because of social media, and 43.1% attributed this to negative patient comments hurting their practice (13).

The context of communication between a doctor and patient is more important than merely just communicating. The standardised messages used in our study incorporated the important factors that influence patient satisfaction. Hamilton et al., found that overall patient satisfaction was predicted reliably by five factors. Meeting pre-operative expectations, satisfaction with pain relief, satisfaction with hospital experience, 12-month Oxford score and lastly pre-operative Oxford score (14). The first three factors broadly determine the patient's overall satisfaction following lower limb joint arthroplasty (14). The standardised cell phone messages used in our study aim to prepare patients for pre- and post-operative expectations, and anticipated pain post-operatively.

Many factors have a bearing when it comes to patient satisfaction and as correctly stated, the patient's satisfaction following a surgical procedure is not only limited to the outcome of the intervention but also by the experience of the event, from pre-operative consultation to post-operative review (15). Patient satisfaction is strongly linked to good communication and a well outlined follow-up plan (16). Data supports that, surgeons who lack in the above-mentioned skills are unlikely to get high ratings from patients (16). Timely health information is an essential management tool to deliver an effective service, especially during the early phases of programme implementation (17). In a study involving 1 541 patients, it was found that patients did not recommend surgeons based on several factors, the most cited reasons being, failure to communicate the patient's medical condition and answer questions thereafter (18). The journey to a near-perfect surgical outcome evidently does not only rely on perfecting the surgical technique but perhaps largely on how we relate and communicate with the patients before, during and after the planned procedure.

This demands that a large fraction of the time is spent investigating what the patient's main problem is and what their wishes are. It entails a long-detailed discussion on the procedure, together with what the realistic expectations might be. Patients should also be made aware of the expectations required from them post-surgery, as well as be given a clear outline of day-to-day rehabilitation goals made available to them as part of informed consent. With this approach many fears can be alleviated, and outcomes changed for the better.

In a pilot study by Kim et al., automated communications, as well as diligent documentation of such communication were assessed (19). As mentioned in this article, before a widespread use of applications (apps) within the field of orthopaedics can be implemented and reach its full potential, a serious issue must be addressed, this being getting both surgeon and patient to accurately record that such an interaction occurred and that plans from that interaction were carried out (19). In some instances, patients would have carried out the plan as per message without documenting it.

Our study aims to evaluate if these short text messages can be used to impact patient satisfaction. We evaluated this using a questionnaire.

Using questionnaires to evaluate results has its strengths and limitations. In designing our questionnaires, we used the three main question types, namely, open-ended, dichotomous and multichotomous (20). If used properly, this is an excellent and cheap method to obtain quantitative data (20). One of the drawbacks, however, is a possible low response rate associated with these (20).

## 1.2 Study Aim and Objectives

The aim of this study was to determine whether peri-operative cell phone massaging patients undergoing TJA at an urban South African public hospital helps improve the satisfaction rate six weeks post-operatively.

The objectives of this study were:

- To compare the satisfaction rate between the groups that received cell phone messages *versus* the group that did not.
- To compare the hospital experience ratings between the two above mentioned groups.
- To compare Patient Reported Outcome Measures (PROMs) between the two groups.

# CHAPTER 2

# METHODOLOGY

## 2.1 Research Question

Does standardised peri-operative cell phone messaging improve patient satisfaction six weeks following TJA?

## 2.2 Research Design

This was a prospective study (Randomised Controlled Trial (RCT)) that ran from 01 September 2019 to 30 October 2021.

## 2.3 Materials and Methods

We conducted a RCT looking at the benefits concerning patient satisfaction of increased communication in the peri-operative period for patients admitted for TJA. This study focused on TKA and THA patients. Communication was done through standardised cell-phone messages to the study group. The messages were sent from a **day before surgery** to **day 3** post-surgery then from week 1 to week 6 post-operatively. The messages required no response from the patients and therefore, no added cost was incurred. Appendix A shows the content of the messages. Ethical approval was granted from the human research ethics committee (HREC) Wits University (HREC number: **M181199**) before recruiting the first patient. Recruitment of patients was done by orthopaedic trainees, with surgeries planned for the rest of the week. Upon confirmation of meeting all the inclusion criteria, patients were recruited and randomised. Questionnaire A (see appendix B) was answered at this stage. Randomisation was done through sealed envelopes labelled with either "**Control**" or "**Study**" inside, patients would pick this out of a box and allocated to whichever group they picked. This method is simple, cost-effective

and all patients stand an equal chance of being allocated to either group. Allocation concealment was established for the outcome assessors and only the principal investigator (PI) had knowledge of group allocation. Outcome assessment was done at 6 weeks after surgery. This included completion of the questionnaire B (see appendix C) and functional scoring using either the HHS (see appendix D) or the OKS (see appendix E) for patients who had THA and TKA, respectively. The completion of questionnaire B was done after functional scoring to preserve allocation concealment and mitigate for bias. As will be noted, in questionnaire B, all questions apply to the study group whilst only some and not all apply to the control group. The scores are also routinely evaluated pre-operatively. Blinding of patients was not done in this study as this would be difficult in a case where one group would have to receive cell-phone messages. The sample size was calculated to be 90 patients, 45 patients on each group. Ten (10) patients were lost to follow-up during the study, therefore, a total of 80 patients remained at final analysis. Demographic data of each patient was collected. This was later kept under an allocated study number. Personal identifying data were kept to a minimum and were always protected. There were no added risks to patients and no costs incurred while conducting this trial. Potential benefits included improved compliance, enhanced understanding, and better clinical and functional outcomes.

## 2.4 Selection Criteria

**Inclusion criteria:**

- All primary TKA/THA patients
- Patients 18 years of age and older
- All patients who own cell phones

**Exclusion criteria:**

- Patients requiring revision surgery
- Trauma patients (Neck of femur fractures-NOF)

- Patients who did not consent for enrolment into the study

## 2.5 Data Analysis

Differences between the group of patients who received a message and those who did not was evaluated using the Pearson's chi-squared test. An independent sample t-test was also used to analyse continuous variables e.g., patient's age, body mass index (BMI) etc. The level of significance was set at $p < 0.05$. All statistical analyses was conducted using IBM SPSS, version 23. Below is the Consolidated Standards of Reporting Trials (Consort) diagram showing progression of participants in the trial (see Figure 2.1).

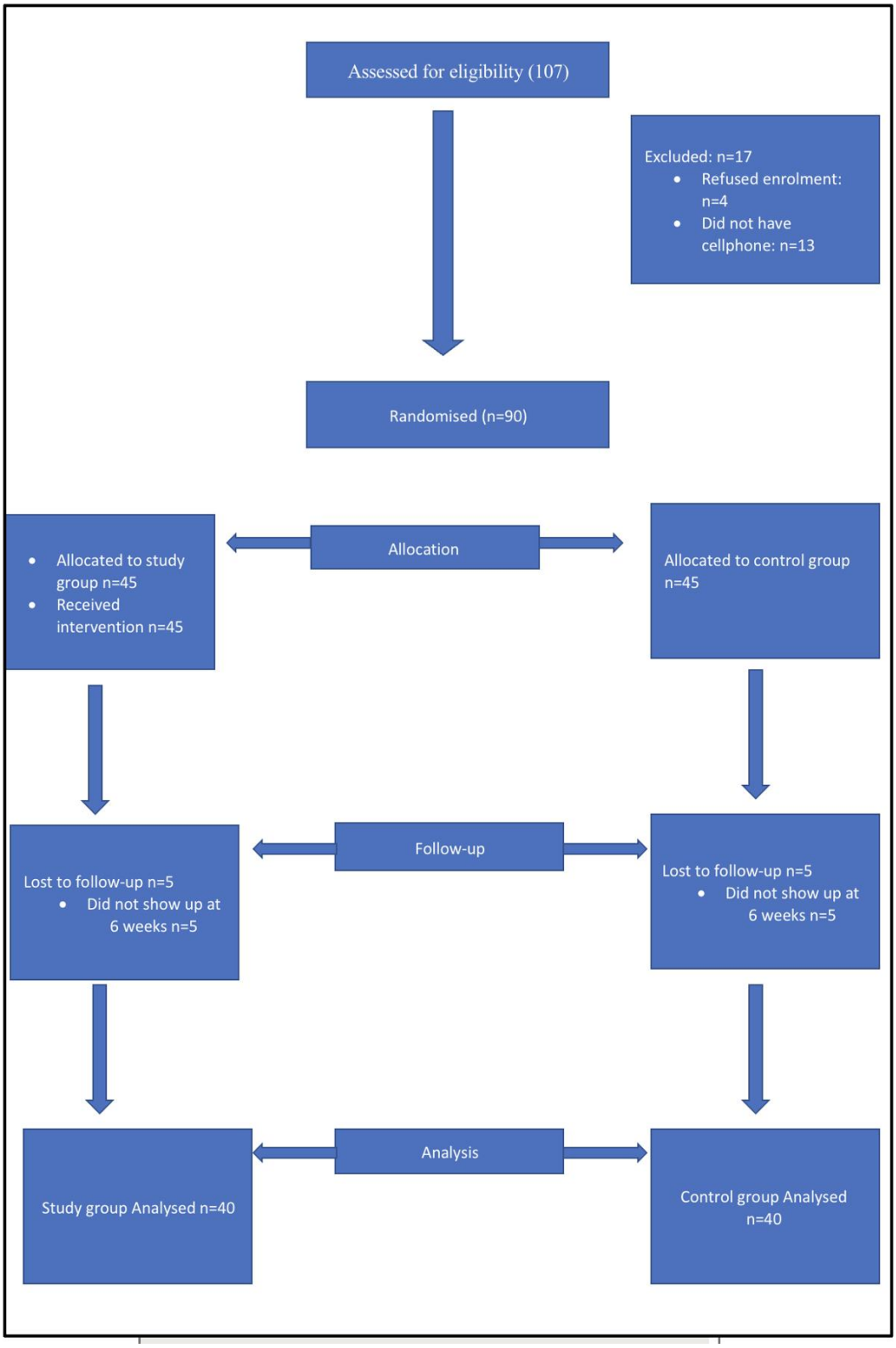



**Figure 2.1:** Consort diagram for our study participants.

# CHAPTER 3

# RESULTS

A total of 90 patients were enrolled to the study with 11% (*n* = 10) patients lost to follow-up, five patients from each group. This left us with 40 patients on each group. Sixty six percent (*n* = 53) were females and 34% (*n* = 27) were males.

### 3.1 In the control group

Thirty percent (*n* = 12) were males and 70% (*n* = 28) females. The average age was 59.2 years (26 – 81 years). Of this group 65% (*n* = 26) lived in a normal house, 25% (*n* = 10) in a flat and 5% (*n* = 2) in informal settlements. Fifty percent of patients were pensioners while 32% (*n* = 13) were unemployed but on a disability grant. Majority of patients in this group [65% (*n* = 26)] were admitted for THA and the remaining 35% (*n* = 14) had TKA. 25% (*n* = 10) had had previous arthroplasty in the contra-lateral knee or hip. The average pre-operative Harris hip score (HHS-1) was 45.2 ± 13.1 (range 10 – 64, median 47) and post-operatively (HHS-2) was 92 ± 8.4 (range 69 – 99, median 95). For the TKA patients, the average pre-operative Oxford knee score (OKS-1) was 21.4 ± 5.5 (range 15 – 28, median 22) while post-operatively (OKS-2) it was 44.8 ± 3.5 (range 39 – 48, median 46)

When asked about the care they received in the hospital, 77.5% (*n* = 31) were satisfied, 17.5% (*n* = 7) were indifferent and 5% (*n* = 2) were dissatisfied Patients were then asked if they would recommend having TJA at CMJAH to their family and/or friends. Eighty percent (*n* = 32) answered yes, 12.5% (*n* = 5) said unlikely and 7.5% (*n* = 3) were indifferent. Seventy five

percent ($n$ = 30) felt that their hospital stay was easier than expected, 10% ($n$ = 4) felt it was worse and the remaining 15% ($n$ = 6) thought it was unaffected. Subjective evaluation of post-operative pain saw 57.5% ($n$ = 23) of patients feeling that it was better than expected, 12.5% ($n$ = 5) thinking it was worse than expected and 30% ($n$ = 12) felt it was as expected. When asked how they felt about their everyday functioning after the operation, 87.5% ($n$ = 35) said it had improved and 12.5% ($n$ = 5) said it was unchanged. None of the patients said that it had worsened.

### 3.2 In the study group

In this group, 37.5% ($n$ = 15) were males and 62.5% ($n$ = 25) females. The average age was 63.8 years (32 – 81). Seventy three percent (72.5%) ($n$ = 29) lived in a normal house, 15% ($n$ = 6) in a flat and 12.5% ($n$ = 5) in informal settlements. Fifty five percent ($n$ = 22) of patients were pensioners while 22.5% ($n$ = 9) were unemployed but on a disability grant. Similarly, to the control group, majority of patients in this group [65% ($n$ = 26)] were admitted for THA and the remaining 35% ($n$ = 14) had TKA. Thirty three percent (32.5%) ($n$ = 13) previously had arthroplasty in the contra-lateral knee or hip. The average HHS-1 was 38.3 ± 11.9 (range 14 – 58, Median 41) and HHS-2 went up to 90.5 ± 9.9 (range 66–99, Median 95). For the TKA patients, the OKS-1 was 13 ± 6.3 (range 0 – 22, Median 13) while OKS-2 was 41.2 ± 6.4 (range 30 – 48, Median 43).

When asked about the care they received in the hospital, 57.5% ($n$ = 23) were satisfied, 22.5% ($n$ = 9) very satisfied, 12.5% ($n$ = 5) indifferent and 7.5% ($n$ = 3) were dissatisfied. Eighty percent (12/15) of males were satisfied [30% (12/40)] compared to a similar 80% (20/25) of females [50% (20/40)]. Of the 13 patients without comorbidities, 11 (84%) were satisfied [27%

(11/40)], like 84% (21/25) of patients with comorbidities [52% (21/40)]. Eighty one percent (18/22) of pensioners [45% (18/40)], 77% (7/9) of patients on a disability grant [17% (7/40)], 50% (3/6) of unemployed patients [7.5% (3/40)] and 100% (3/3) of employed patients [7.5% (3/40)] were satisfied. Patients were then asked if they would recommend having TJA at CMJAH to their family and/or friends. Fifty eight percent (57.5%) (*n* = 23) answered yes, 20% (*n* = 8) said highly recommend it, 15% (*n* = 6) were indifferent and 7.5% (*n* = 3) said unlikely. Seventy eight percent (77.5%) (*n* = 31) felt that their hospital stay was easier than expected, 22.5% (*n* = 9) felt it was unaffected. No patient felt it was worse. Ninety percent (*n* = 36) of patients found the messages assisted them with rehabilitation. Subjective evaluation of post-operative pain revealed 72.5% (*n* = 29) of patients feeling that it was better than expected, 20% (*n* = 8) thinking it was as expected and 7.5% (*n* = 3) felt it was worse than expected. When asked how they felt about their everyday functioning after the operation, 92.5% (*n* = 37) said it had improved and 7.5% (*n* = 3) said it was unchanged. None of the patients said that it had worsened. Majority of the patients [87.5% (*n* = 35)] received all 10 messages whilst 12.5% (*n* = 5) received less than 10 of the messages. 52.5% (*n* = 21) were happy most of the time with receiving the messages, 25% (*n* = 10) all the time, 15% (*n* = 6) some of the time, 5% (*n* = 2) were indifferent and 2.5% (*n* = 1) were not at all happy to receive the messages. In this group, 55% (*n* = 22) found the messages very helpful while 25% (*n* = 10) found them extremely helpful. To 5% (*n* = 2) of the patients they made no difference and 15% (*n* = 6) were undecided. The messages were easy to understand in 95% (*n* = 38) of the study group and only 5% (*n* = 2) admitted to not understanding them well. 62.5% (*n* = 25) were accepting of having the messages in English, 15% (*n* = 6) in isiZulu and the 22.5% (*n* = 9) was shared between Pedi, Sotho, and Xhosa. Patients were asked if the messages helped with rehabilitation. Ninety percent (*n* = 36) believed they were helpful and only 10% (*n* = 4) answered no. Concerning wound care, 62.5% (*n* = 25) said the messages assisted with wound care and 37.5% (*n* = 15)

found no benefit in that regard. Overall, 52.5% ($n$ = 22) said yes, they would recommend the messages for other fellow patients, 25% ($n$ = 10) would highly recommend them whilst 12.5% ($n$ = 5) and 10% ($n$ = 4) were "indifferent" and "unlikely to", respectively. Demographic data are as shown in Table 3.1.

**Table 3.1**: Baseline Patient Demographic and Clinical Characteristics for the 2 groups

| | | **Study group** | **Control group** |
|---|---|---|---|
| **Gender:** | Male | 37.5% ($n$ = 15) | 30% ($n$ = 12) |
| | Female | 62.5% ($n$ = 25) | 70% ($n$ = 28) |
| **Age** | | 63.8 (32 – 81) | 59.2 (26 – 81) |
| **Total Hip Arthroplasty** | | 65% ($n$ = 26) | 65% ($n$ = 26) |
| **Total Knee Arthroplasty** | | 35% ($n$ = 14) | 35% ($n$ = 14) |
| **Comorbidities** | 1 | 50% ($n$ = 20) | 32.5% ($n$ = 13) |
| | 2 | 5% ($n$ = 2) | 5% ($n$ = 2) |

### 3.3 Study group *versus* control group

Paired samples t-test indicated that mean difference of paired observations of the HHS-1 between control group and study group was not statistically significant ($p > 0.05$) i.e., $p$-value = 0.07. On reviewing HHS-2 between the groups, the Paired samples t-test indicated that mean difference of paired observations of the HHS-2 between control group and study group was not statistically significant ($p > 0.05$) i.e., $p$-value = 0.61.

Of note, the Paired samples t-test indicated that mean difference of paired observations of the OKS-1 between control group and study group was statistically significant ($p < 0.05$) i.e.,

*p*-value = 0.00000032. More interestingly perhaps, the Paired samples t-test indicated that mean difference of paired observations of the OKS-2 between control group and study group was statistically significant ($p < 0.05$) i.e., *p*-value = 0.00086.

The Chi-squared test indicated that there was no statistically significant difference between Hospital stay experience of patients in the control group and the Hospital Stay experience of the Study group, *p*-value > 0.05 i.e., $p = 0.10$. This was also true for post-operative pain between the 2 groups, *p*-value > 0.05 i.e., $p = 0.37$. Chi-squared test indicated that there was no statistically significant difference between the patients' subjective post-operative everyday function in the control group and that of the Study group, *p*-value > 0.05 i.e., $p = 0.46$. Figure 3.1 demonstrates the outcome for the responses on hospital care if they would recommend the unit for TJA and hospital stay. These displayed no statistical difference. Figures 3.2 and 3.3 demonstrate the pre-operative and post-operative HHS and OKS between the two groups, respectively.

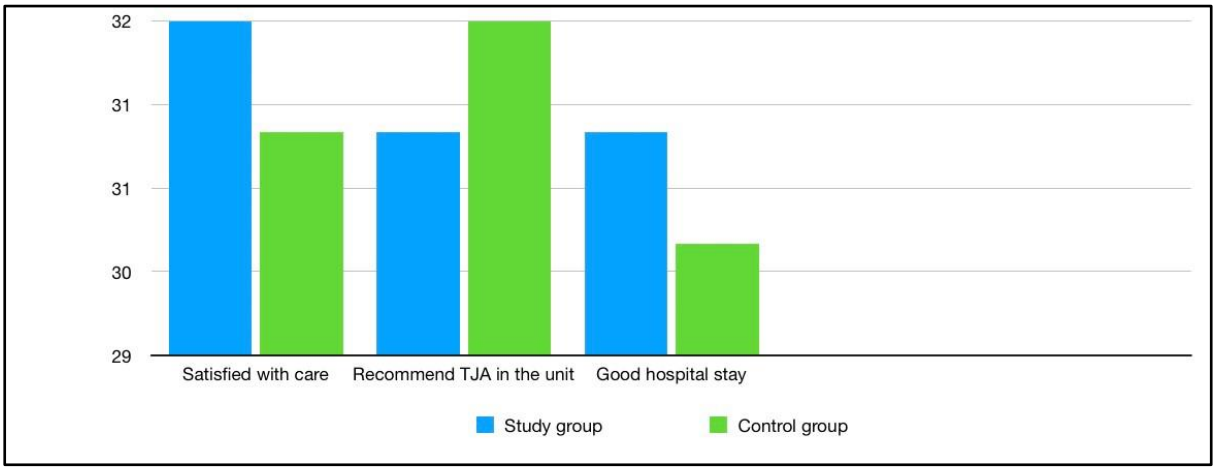



**Figure 3.1:** Illustration of the absolute number of patients that were satisfied with care, recommend TJA in the unit for other patients and patients who had a good hospital stay. Each group had 40 patients.

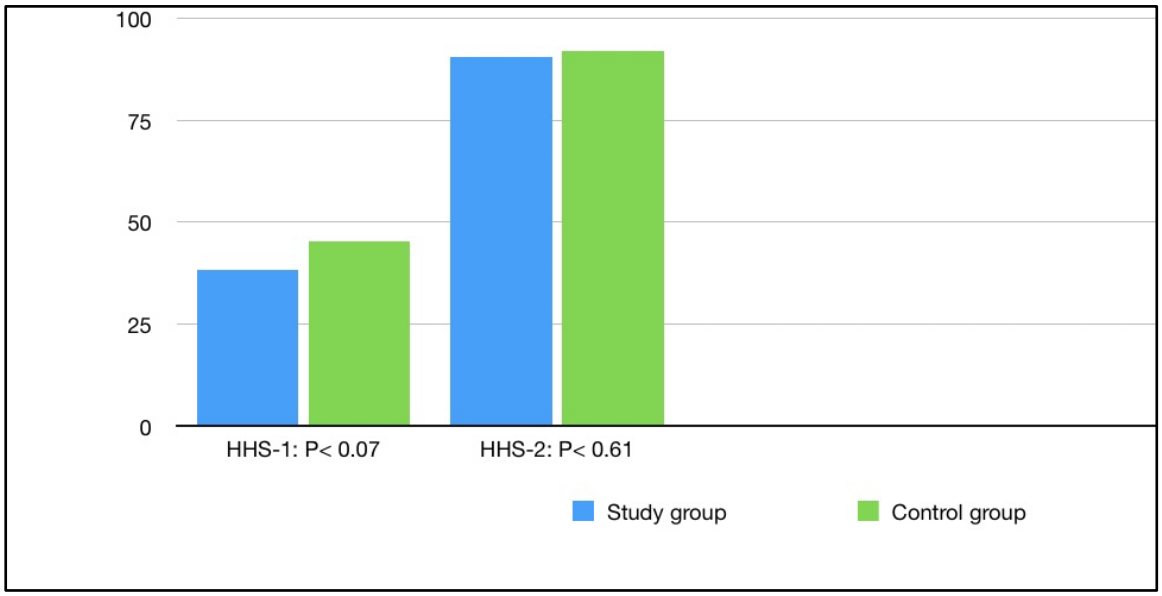



**Figure 3.2**: Illustration of the pre-operative HHS-1 and the post-operative HHS-2 between the two groups.

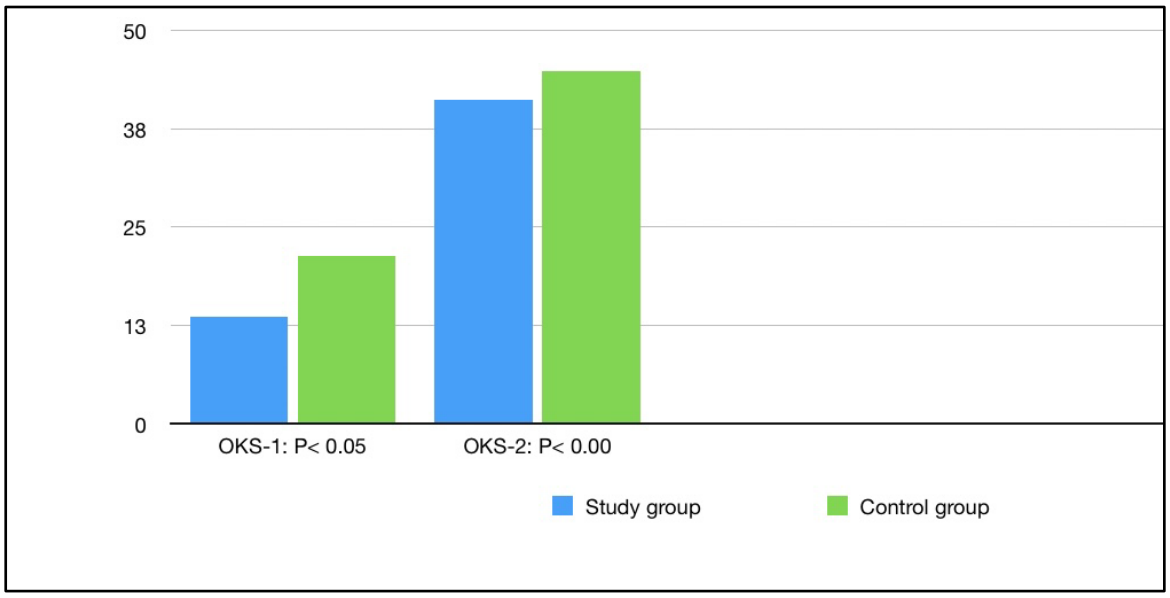



**Figure 3.3:** Illustration of the pre-operative OKS-1 and the post-operative OKS-2 between the two groups.

# CHAPTER 4

# DISCUSSION

We undertook this study to determine whether peri-operative cell phone massaging patients undergoing TJA at an urban South African public hospital helps improve the satisfaction rate six weeks post-operatively. This further evaluated their impression of the care received and functional scoring. The era of arthroplasty thrives on value-based reimbursement and high-volume surgical procedures, and thus patient experience is increasingly important (21). This is what makes this trial particularly important. A more sophisticated method in a form of downloadable apps could have been used however, a simpler and a more affordable method was chosen in the hope to enhance compliance and reduce cost to patients. This becomes very important considering the patient demographics of the study, largely older patients living on pension money.

More patients in the study group were satisfied with the care received than those in the control group (see Figure 3.1). However, this did not meet statistical significance, *p*-value > 0.05 i.e., $p = 0.76$. A more detailed look into this however does reveal that the study group had a higher quality of satisfaction with 9 patients in the study group being "*very satisfied"* with the care received *versus* none in the control group. The text messages played a positive role in these patients. A systematic review came to a similar conclusion as our study, that patient satisfaction was equivalent in both groups (22). Patient satisfaction is not simple to measure and has multifactorial factors. Statistically significant factors also include the patients' communication with the nursing staff (5). This can explain why this intervention was not outrightly superior to routine practice. Some patients perhaps would do better with a more interactive platform than just standard messages that they cannot respond to.

For the most part our results seem to show dissimilar outcomes to what is published by Campbell et al. (21). Their trial showed the intervention group to outrightly do better than the control group. The Harris hip scores of the 2 groups were very similar (see Figure 3.2). These did not display any statistically significant difference. The groups essentially started off with very similar disability levels. Both groups improved remarkably but unsurprisingly, there was no statistically significant difference in their post-operative Harris hip scores. Generally, THA patients are better functionally than TKA patients (1).

Of note however, the Paired samples t-test indicated that mean difference of paired observations of the OKS-2 between the groups is statistically significant ($p < 0.05$) i.e., $p$-value = 0.00086 favouring the control group (see Figure 3.3). It must be noted however that the study group started off with a statistically significantly lower Oxford knee score pre-operatively. On average, the change in OKS was by 23.4 points for the control group and by 28 points for the study group. Literature shows that patients on the intervention group exercise 8.6 minutes more than the control group and have a better knee range of motion (ROM) at 3 weeks (21). This effect is however non-existent at 6 weeks and the groups have a similar ROM (21). Non-modifiable patient factors were very similar between the groups as shown in Table 3.1.

In absolute numbers more patients in the control group responded positively to the question of recommending the unit to their family/friends (see Figure 3.1). However, not reflected on the graph is that 8 patients in the study group would "*highly recommend"* having a TJA in the institution *versus* none in the control group. This is an important finding but very difficult to attribute to the intervention. Worth acknowledging, nonetheless. Bishop et al., found that even with brief lapses in communication, "word-of-mouth" recommendation was reduced (6). Contrary to routine practice, the intervention provided patients with weekly instructions for the

first 6 weeks post-operatively. This certainly bridged these potential lapses and might be responsible for the experienced differences amongst the groups.

Hospital stay was similar for both groups (see Figure 3.1). The Chi-squared test indicated no statistically significant difference, $p$-value > 0.05 i.e., $p = 0.10$ for this parameter. Evaluation of subjective parameters such as this one is difficult with just quantitative methods. An in-depth engagement using qualitative methods might yield more valuable results.

The use of the intervention was extended to the rehabilitation period. Our study had 90% of the intervention group admitting that the text messages helped with rehabilitation. In a systematic review, Mckeon et al., concluded that Telerehabilitation following lower-extremity joint replacement is less expensive compared with in-person physical therapy, with equivalent outcomes and patient satisfaction (22). Our results are in keeping with this finding. Similar work done in the first world yielded largely positive results (21). To a degree this examines this method in a third world context.

Eighty three percent of the studies report more than 80% satisfaction rate for TKA and up to 90% satisfaction rate for THA in separate studies (1). While an improvement in both these statistics is the goal, it is much more important for TKA patients. This trial has shown this group of patients to have been the ones that benefited the most from this intervention.

Surgeons might be anxious about limited physical post-operative clinic visits for TJA patients. The anxiety might be brought up by the potential of not picking up complications early enough or not spending the desired amount of time pre-operatively counseling patients. The intervention employed in this trial certainly added no harm to patients and even though not formally evaluated, no peculiar complications were attached to it. In a society that is moving

towards less physical contact because of the Covid-19 pandemic, such measures are worth exploring. The methodology used in our study allowed us to determine if the patient received correspondence from the investigators, however, patients being able to reply to that correspondence in real time was beyond the scope of this project. The mode of communication employed in this study is not peculiar to arthroplasty nor is it to the field of orthopaedics. We chose it for its simplicity and accessibility to many patients. To the best of our knowledge, this has not been conducted locally in SA. Published literature examines this question largely in the first world.

The consideration of language was examined. Our institution treats patients from different linguistic backgrounds. In a country like South Africa with 11 official languages, many instructions can be lost in translation as not every patient is fluent in English. Majority of the patients (62.5%) were happy to keep the messages in English. This is not particularly surprising. Our institution is situated in urban Johannesburg and our drainage areas are more contemporary. The outcome might have been different for the rural parts of SA where the population is older and with little formal education.

This trial is not without limitations. The sample size is one of those. Perhaps a future trial can be designed to include a larger sample size. This might have a bearing on producing a different outcome. Importantly, allocation concealment and patient blinding were not done because of the nature of the intervention. This does introduce selection bias which has a significant impact on results. This exaggerates the estimate of the effect size of interventions (23).

### 4.1 Recommendations

Based on the results of this study the following recommendations are made. The first one is to recommend a larger sample-sized study to be conducted. Secondly, and linked to the first recommendation, a national multi-centre trial should be undertaken to evaluate if the outcomes would be unchanged given differing patient demographics. The population dynamics and socioeconomic differences that exist within different regions in SA make this a valid point. The outcomes experienced in one region do not reflect the general experience.

Our third recommendation is that a formal qualitative component be incorporated in the study design to evaluate patient satisfaction. The question of satisfaction is such a personal experience that it cannot be fully answered by quantitative methods. This could take the path of generating theories through the grounded theory methodology or exploring details of personal lived experiences through interpretative phenomenological analysis (IPA).

As a fourth recommendation we strongly advice Public and Patient Involvement (PPI) in every stage of the study design.

Based on the results we would recommend that this intervention be used with caution and with a willing patient that can be fully engaged with its requirements. Until the above-mentioned recommendations are met, we cannot recommend the intervention to be used routinely.

# CHAPTER 5

# CONCLUSION

The satisfaction rate of patients that received short text messages to their cell phones is equivalent and comparable to that of patients using traditional forms of communication. The quality of the satisfaction is superior for SMS patients than it is for their counterparts. Patients receiving peri-operative SMSs while undergoing TKA display a greater improvement (OKS) functionally. The function of patients that received peri-operative short text messages while undergoing THA is equivalent and comparable to the patients using traditional forms of communication. The use of short text messages as a tool for increased peri-operative communication is safe for patients undergoing TJA, surgeons and patients need not have anxiety about using this platform. It is simple, convenient and patients find it easy to understand and it also limits physical contact. Peri-operative cell-phone short text messages are beneficial for patients undergoing TJA.

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## Appendices

### Appendix A: Content of short text messages

| Peri-operative day (Hip) | Message content |
|---|---|
| Day before surgery | -Good afternoon, tomorrow is your surgery day.<br>-Please kindly do not eat from 22h00 tonight<br>-After the operation you will be transferred back to ward 374 and a Dr will see you in the afternoon<br>-Should you feel unbearable pain please inform our kind nursing staff |
| D1 post-operative | -Good morning, today you are expected to be able to walk 10 metres with a frame and sit in a chair.<br>-Please kindly keep the wound dressing dry and inform staff if at all worried<br>-Pain is expected to improve today and please request clexane (blood thinner) from nursing staff |
| D2 post-operative | -Good morning, today you are expected to be able to walk to the toilet with crutches and improve thigh muscle strength<br>-Greater improvement to your pain is expected today<br>-Kindly inform our staff members with any concern |
| D3 post-operative | -Good morning, today you are expected to be able to walk around the ward alone with crutches<br>- You will be taken to walk stairs |

| | |
|---|---|
| | -Please inspect your wound dressing that it's clean and dry<br>-You are getting closer to your day of discharge. |

| **Peri-operative day (knee)** | **Message content** |
|---|---|
| Day before surgery | -Good afternoon, tomorrow is your surgery day.<br>-Please kindly do not eat from 22h00 tonight<br>-After the operation you will be transferred back to ward 374 and a Dr will see you in the afternoon<br>-Should you feel unbearable pain please inform our kind nursing staff |
| D1 post-operative | -Good morning, today you are expected to be able to walk 10 metres with a frame, sit in a chair and bend your knee to a sitting position with assistance<br>-Please kindly keep the wound dressing dry and inform staff if at all worried<br>-Pain is expected to improve today and please request clexane (blood thinner) from nursing staff |
| D2 post-operative | -Good morning, today you are expected to be able to walk to the toilet with little help.<br>-Improve thigh muscle strength and bend your knee to sitting position without assistance<br>-Greater improvement to your pain is expected today |

| | |
|---|---|
| | -Kindly inform our staff members with any concern |
| D3 post-operative | -Good morning, today you are expected to be able to walk around the ward alone with crutches and on the stairs<br>-Please inspect your wound dressing that it's clean and dry<br>-You are getting closer to your day of discharge. |

| | |
|---|---|
| 1st week post-operative | -Please continue to mobilise as per physiotherapist's instruction<br>-Pain should be much reduced now<br>-When you undress, remove clothes from your surgery side last.<br>-Sit in a firm chair with a straight back and armrests. Avoid soft chairs, rocking chairs, stools, or sofas. |
| 2nd week post-operative | -Kindly monitor that your wound dressing remains dry<br>-DO NOT cross your legs.<br>-Do not sit in the same position for more than 30 to 40 minutes at a time<br>-Keep your feet and knees pointed straight ahead, not turned in or out. |
| 3rd week post-operative | -Please remember to present to your local clinic to have skin staples removed<br>-Avoid chairs that are too low<br>-You may stand in the shower if you like.<br>-Do not dress standing up. Sit on a chair or the edge of your bed if it is stable |

| | |
|---|---|
| 4th week post-operative | -This is your last week of the clexane injection<br>-When you are going up the stairs, step first with your leg on the side that did not have surgery.<br>-When you are going down, step first with your leg on the side that had surgery.<br>-Do not bend too far forward from your waist or pull your leg up past your waist. |
| 5th week post-operative | -Please remember to take cautions as instructed by the physiotherapist<br>-Use your crutches or walker until your doctor tells you it is OK to stop using them.<br>-Take small steps when you are turning<br>-Use an elevated toilet seat to keep your knees lower than your hips |
| 6th week post-operative | -A friendly reminder that you are due for a clinic review at CMJAH this week<br>-Do not drive yourself.<br>-Break up long car trips. Stop, get out, and walk about every 2 hours<br>-Car seats should not be too low. Sit on a pillow if you need to. |

Messages from the 1st week to the 6th week post-operatively apply to both Total Knee Replacement and Total Hip Replacement patients.

**Appendix B: Questionnaire A**

Study number:_____ Date of Birth_____ Age:_____

Sex: ☐Male ☐Female

Highest Level of Education:

☐Primary School ☐High School ☐Matric ☐Tertiary education

Domicile: ☐House ☐Flat ☐Informal structure Lives: ☐City ☐Town ☐Rural area

Employment:

☐Employed ☐Unemployed on DG ☐Unemployed NOT on DG ☐Pensioner

Occupation:_____

PMH: ☐Diabetes ☐Epilepsy ☐Asthma ☐Thyroid ☐Hypertension ☐Cardiac ☐Stroke

Do you use Spectacles: ☐All the time ☐Intermittently ☐contact lenses mostly

If intermittent, for ☐driving ☐reading ☐TV ☐other

Eye problems: ☐Glaucoma ☐ Cataracts ☐Retinal problems ☐Previous ocular trauma ☐ Other

Walking aids BEFORE surgery: ☐none ☐1 cane/crutch ☐2 crutches ☐walker ☐rollator

Currently Involved joint: ☐Left ☐Right ☐THA ☐TKA

Previous Arthroplasty Surgery: ☐Left ☐Right THA ☐Left ☐Right TKA

Do you own have a phone? ☐Yes ☐No

If yes, what type of cell phone? ☐Smartphone ☐Feature "standard" cell phone

If no, why not? ☐No need ☐Cannot afford one ☐Lost/stolen ☐Cannot use ☐other

Do you have a ☐cell phone contract ☐pay-as-you go ☐rely on sent airtime ☐other?

What do you MOSTLY use your cell phone for?

☐Personal voice calls ☐Work voice calls ☐Personal Instant messaging ☐Emergency only

☐Work instant messaging

Are you able to receive SMSs? ☐Yes ☐No

**Appendix C: Questionnaire B**

**Study number:**…….

1) Do you still have your phone?

   ☐ Yes
   ☐ No

   If no, why not?

   ☐ Stolen

   ☐ Broken

   ☐ Misplaced

   ☐ Other

2) Did you receive the SMSs?

   ☐ Yes, received 10 SMSs

   ☐ Yes, received less than 10 SMSs

   ☐ No, I did not

   ☐ Other…

Please rate as per labelled options for the questions below by circling your best option.

3) Did you enjoy receiving these text messages?

| | | | | |
|---|---|---|---|---|
| Not at all | Some of the time | Indifferent | Most of the time | Yes, all the time |

4) Did you find the text messages helpful?

| | | | | |
|---|---|---|---|---|
| No, waste | No, made no | Undecided | Yes, very helpful | Yes, extremely |

5) Were you satisfied with the care you received at CMJAH?

| | | | | |
|---|---|---|---|---|
| Very | Dissatisfied | Indifferent | Satisfied | Very satisfied |

6) Would you recommend family/friends have their TJA at CMJAH?

| | | | | |
|---|---|---|---|---|
| Never | Unlikely | Indifferent | Yes | Highly |

7) Would you recommend these text messages for other fellow patients?

| | | | | |
|---|---|---|---|---|
| Never | Unlikely | Indifferent | Yes | Highly |

☐

8) Were the messages easy to understand?
   - ❖ Yes
   - ❖ No
9) Would you prefer these messages in a different language?
   - ❖ Yes
   - ❖ No
10) If yes to question 9, state which language you would prefer.
11) Did the messages make your hospital stay:
   - ❖ Easier
   - ❖ Worse
   - ❖ Unaffected
12) Was the pain after the operation:
   - ❖ Better than expected
   - ❖ Worse than expected
   - ❖ As expected
13) Did you find the messages were clear about the rehabilitation progress expected?
   - ❖ Yes
   - ❖ No
14) Did the messages help you with wound care?
   - ❖ Yes

- ❖ No

15) Since the operation has your everyday function:
- ❖ Improved
- ❖ Worse
- ❖ Unchanged

## Appendix D: Harris Hip score

**Section 1**

| Pain | Support |
|---|---|
| ◯ None, or ignores it | ◯ None |
| ◯ Slight, occasional, no compromise in activity | ◯ Cane/Walking stick for long walks |
| ◯ Mild pain, no effect on average activities, rarely moderate pain with unusual activity, may take aspirin | ◯ Cane/Walking stick most of the time |
| ◯ Moderate pain, tolerable but makes concessions to pain. Some limitations of ordinary activity or work. May require occasional pain medication stronger than aspirin | ◯ One crutch |
| ◯ Marked pain, serious limitation of activities | ◯ Two Canes/Walking sticks |
| ◯ Totally disabled, crippled, pain in bed, bedridden | ◯ Two crutches or not able to walk |

| Distance walked | Limp |
|---|---|
| ◯ Unlimited | ◯ None |
| ◯ Six blocks (30 minutes) | ◯ Slight |
| ◯ Two or three blocks (10 - 15 minutes) | ◯ Moderate |
| ◯ Indoors only | ◯ Severe or unable to walk |
| ◯ Bed and chair only | |

| Activities - shoes, socks | Stairs |
|---|---|
| ◯ With ease | ◯ Normally without using a railing |
| ◯ With difficulty | ◯ Normally using a railing |
| ◯ Unable to fit or tie | ◯ In any manner |
| | ◯ Unable to do stairs |

| Public transportation | Sitting |
|---|---|
| ◯ Able to use transportation (bus) | ◯ Comfortably, ordinary chair for one hour |
| ◯ Unable to use public transportation (bus) | ◯ On a high chair for 30 minutes |
| | ◯ Unable to sit comfortably on any chair |

**To score this section all four must be 'yes', then get 4 points. Nb. Not 1 point for each four or nothing.**

**Section 2**

**Does your patient have ALL of the following: -**

◯ yes
◯ no

Less than 30degrees of fixed flexion
Less than 10 degrees of fixed int rotation in extension
Less than 10 degrees of fixed adduction
Limb length discrepancy less than 3.2 cm (1.5 inches)

**Section 3 - Motion**

| Total degrees of Flexion | Total degrees of Abduction |
|---|---|
| ◯ None | ◯ None |
| ◯ 0 >8 | ◯ 0 > 5 |
| ◯ 8 > 16 | ◯ 5 > 10 |
| ◯ 16 > 24 | ◯ 10 > 15 |
| ◯ 24 > 32 | ◯ 15 > 20 |
| ◯ 32 > 40 | **Total degrees of Ext Rotation** |
| ◯ 40 > 45 | ◯ None |
| ◯ 45 > 55 | ◯ 0 > 5 |
| ◯ 55 > 65 | ◯ 5 > 10 |
| ◯ 65 > 70 | ◯ 10 > 15 |
| ◯ 70 > 75 | **Total degrees of Adduction** |
| ◯ 75 > 80 | ◯ None |
| ◯ 80 > 90 | ◯ 0 > 5 |
| ◯ 90 > 100 | ◯ 5 > 10 |
| ◯ 100 > 110 | ◯ 10 > 15 |

# Appendix E: Oxford Knee score

**During the past 4 weeks.....**

**1. How would you describe the pain you usually have in your knee?**

- ◯ None
- ◯ Very mild
- ◯ Mild
- ◯ Moderate
- ◯ Severe

**2. Have you had any trouble washing and drying yourself (all over) because of your knee?**

- ◯ No trouble at all
- ◯ Very little trouble
- ◯ Moderate trouble
- ◯ Extreme difficulty
- ◯ Impossible to do

**3. Have you had any trouble getting in and out of the car or using public transport because of your knee? (With or without a stick)**

- ◯ No trouble at all
- ◯ Very little trouble
- ◯ Moderate trouble
- ◯ Extreme difficulty
- ◯ Impossible to do

**4. For how long are you able to walk before the pain in your knee becomes s eve re? (With or without a stick)**

- ◯ No pain > 60 min
- ◯ 16 - 60 minutes
- ◯ 5 - 15 minutes
- ◯ Around the house only
- ◯ Not at all - severe on walking

**5. After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?**

- ◯ Not at all painful
- ◯ Slightly painful
- ◯ Moderately pain
- ◯ Very painful
- ◯ Unbearable

**6. Have you been limping when walking, because of your knee?**

- ◯ Rarely / never
- ◯ Sometimes or just at first
- ◯ Often, not just at first
- ◯ Most of the time
- ◯ All of the time

**7. Could you kneel down and get up again afterwards?**

- ◯ Yes, easily
- ◯ With little difficulty
- ◯ With moderate difficulty
- ◯ With extreme difficulty
- ◯ No, impossible

**8. Are you troubled by pain in your knee at night in bed?**

- ◯ Not at all
- ◯ Only one or two nights
- ◯ Some nights
- ◯ Most nights
- ◯ Every night

**9. How much has pain from your knee interfered with your usual work? (including housework)**

- ◯ Not at all
- ◯ A little bit
- ◯ Moderately
- ◯ Greatly
- ◯ Totally

**10. Have you felt that your knee might suddenly ĝgive awayĝ or let you down?**

- ◯ Rarely / Never
- ◯ Sometimes or just at first
- ◯ Often, not at first
- ◯ Most of the time
- ◯ All the time

**11. Could you do household shopping on your own?**

- ◯ Yes, easily
- ◯ With little difficulty
- ◯ With moderate difficulty
- ◯ With extreme difficulty
- ◯ No, impossible

**12. Could you walk down a flight of stairs?**

- ◯ Yes, easily
- ◯ With little difficulty
- ◯ With moderate difficulty
- ◯ With extreme difficulty
- ◯ No, impossible

**Appendix F: Permission to use the Oxford Knee Score**

On Wednesday, December 22, 2021, <healthoutcomes@innovation.ox.ac.uk> wrote:

**Order 00OKS-946988 has been approved**

Dear Philani Ntombela

I am pleased to inform you that your request to use the PRO measure was successful and you now have a licence To use it.

You can download your documents here

If you have any further questions please contact Clinical Outcomes at healthoutcomes@innovation.ox.ac.uk

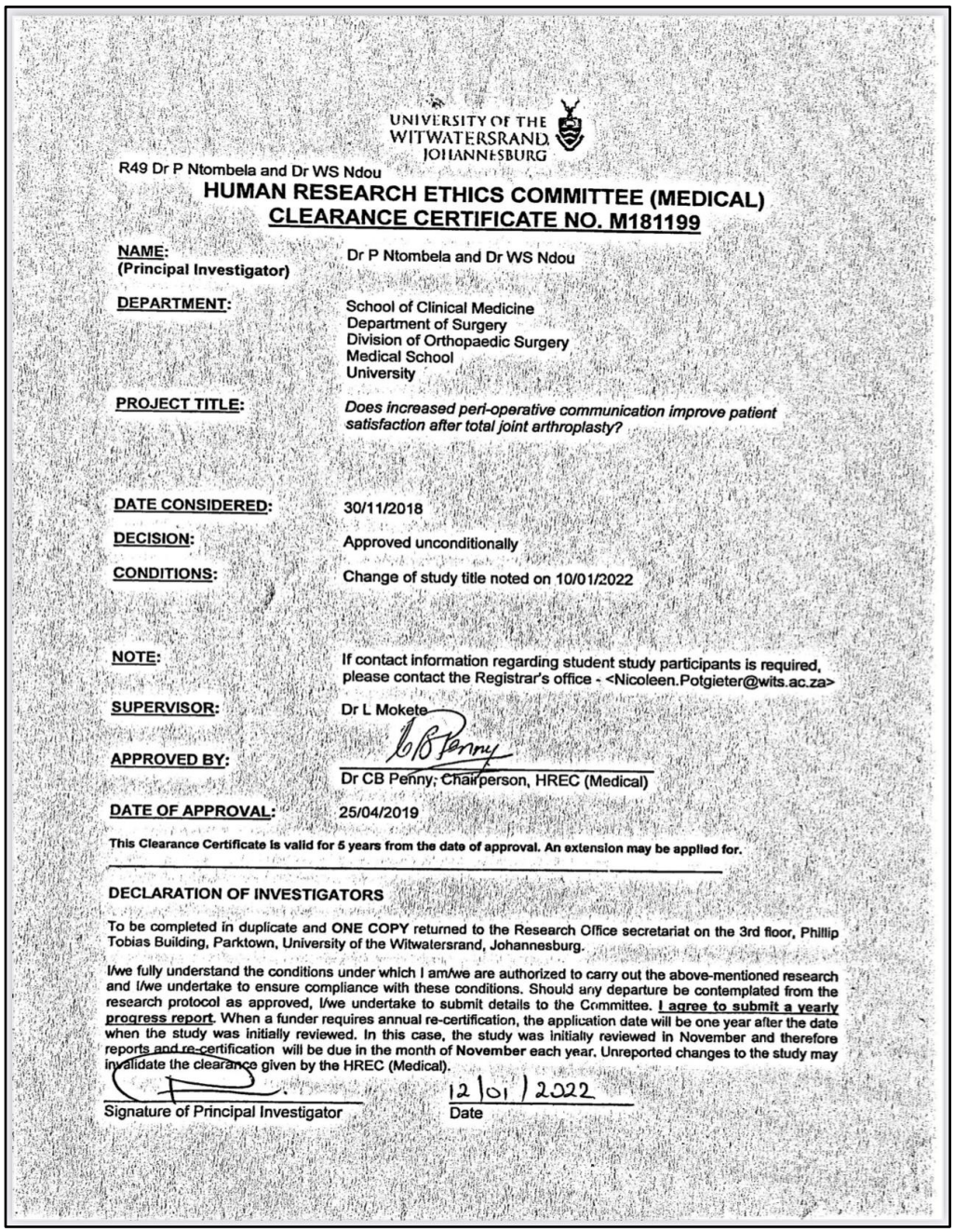
Under the T&C's of the granted copyright licence:

1. You should only use the licenced questionnaire for the purpose you informed us of, the details of which are in the attached PDF
2. You shall not translate or otherwise adapt the questionnaire (including adaption to digital delivery format) without the written permission of the Clinical Outcomes team at Oxford University Innovation. However, you are allowed to add your own pre-amble and post questionnaire items or information (Patient ID, D.O.B., sex, co-morbidities etc) as well as logo for example, so long as you do not interfere with the licensed Questionnaire format, order of questions, item content including responses or styling.
3. 3) If you have requested a licence to digitally reproduce the Questionnaire as an eCOA / ePRO then, although the granted licence does give you permissions to now develop the faithful reproduction of the Questionnaire (using the guidelines we have provided), you are still required to secure written authorisation (following review) of a faithful reproduction from the Clinical Outcomes team before publication.

Regards

Clinical Outcomes at Oxford University Innovation

## Appendix G: HREC certificate



UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R49 Dr P Ntombela and Dr WS Ndou

**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)**

**CLEARANCE CERTIFICATE NO. M181199**

| | |
|---|---|
| **NAME:** (Principal Investigator) | Dr P Ntombela and Dr WS Ndou |
| **DEPARTMENT:** | School of Clinical Medicine<br>Department of Surgery<br>Division of Orthopaedic Surgery<br>Medical School<br>University |
| **PROJECT TITLE:** | *Does increased peri-operative communication improve patient satisfaction after total joint arthroplasty?* |
| **DATE CONSIDERED:** | 30/11/2018 |
| **DECISION:** | Approved unconditionally |
| **CONDITIONS:** | Change of study title noted on 10/01/2022 |
| **NOTE:** | If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za> |
| **SUPERVISOR:** | Dr L Mokete |
| **APPROVED BY:** | Dr CB Penny, Chairperson, HREC (Medical) |
| **DATE OF APPROVAL:** | 25/04/2019 |

**This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.**

**DECLARATION OF INVESTIGATORS**

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report.** When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in November and therefore reports and re-certification will be due in the month of **November** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

12/01/2022
Date