Social Science & Medicine

Randomised controlled trial assessing the safety, efficacy and cost-effectiveness of the Maxm Skate post-operative rehabilitation device and program following total knee arthroplasty

--Manuscript Draft--

Manuscript Number:	
Article Type:	Research paper
Keywords:	Total knee arthroplasty, Rehabilitation, Home-based, Range of motion, Cost-effectiveness
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Abstract:	B ackground: Physical rehabilitation is required to enhance functional outcome and recovery following total knee arthroplasty (TKA). Rehabilitation is commonly provided one-to-one in an outpatient setting, which is resource-intensive. Less costly alternatives, such as home-based rehabilitation, provide similar functional outcomes. Objective: To compare the safety, efficacy and cost-effectiveness of a home-based rehabilitation program (MAXM) using the Maxm Skate exercise device and iOS application to standard care (SC) rehabilitation post-TKA in a private hospital setting. Methods : Single-blinded, randomised controlled trial. Participants were randomised to MAXM or SC. Participants randomised to MAXM used the skate device, accompanying iOS Application and sensors to complete MAXM exercises. The primary outcome was gains in range of motion (ROM) at 12 weeks post-TKA. Secondary outcomes included patient-reported outcomes and associated costs. Costs were assessed from a healthcare sector perspective . Results: Analyses were performed when N=73 (MAXM:36/73; SC: 37/73) participants completed their 12-week follow-up. Continued participant recruitment was deemed futile given the cancellation of elective surgery at the onset of the COVID-19 pandemic in Australia. The device was safe. MAXM ROM mean gains at 12 weeks postoperative were significantly greater than SC, 43.7 0 (SD 3.9) compared to 30.9 0 (SD 1.6) (p-value = 0.005), with a mean difference of 12.9 0 (CI: 3.9, 21.8) and a quality-adjusted life-year (QALY) gain of mean 0.19 (SD 0.05) compared to 0.11 (SD 0.05), with a mean difference of 0.007 (CI: -0.007, 0.021). MAXM was cost-effective compared to SC as it was cheaper by AUD 8,316/patient (AUD 26,069/patient in sensitivity analyses) and more effective in terms of gains in ROM and QALYs. Conclusion : This study demonstrates that MAXM is a safe, cost-effective method to improve ROM, strength and function and reduce pain post-TKA.
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Manuscript title: Randomised Controlled Trial Assessing the Safety, Efficacy and Cost-Effectiveness of The MAXM Skate Postoperative Rehabilitation Device and Program Following Total Knee Arthroplasty

Running title: Cost-Effectiveness of MAXM Skate Device

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Financial disclosure: In-kind support was received for research-related activities from the International Musculoskeletal Research Institute Incorporated (IMRI), supplemented by the South Australian Innovation Project Grant. In-kind support received for physiotherapist time and resources from Flinders Private Hospital, Adelaide, South Australia. In-kind support from Maxm Skate Pty Ltd (provision of the Maxm Skate product). Maxm Skate Pty Ltd provided financial support to meet the costs of the health economics evaluation and study insurance.

Precis: This study presents the first economic evaluation in Australia to demonstrate that the MAXM program is a cost-effective method to improve ROM, strength and function and reduce pain post-TKA

Abstract

Background: Physical rehabilitation is required to enhance functional outcome and recovery following total knee arthroplasty (TKA). Rehabilitation is commonly provided one-to-one in an outpatient setting, which is resource-intensive. Less costly alternatives, such as home-based rehabilitation, provide similar functional outcomes.

Objective: To compare the safety, efficacy and cost-effectiveness of a home-based rehabilitation program (MAXM) using the Maxm Skate exercise device and iOS application to standard care (SC) rehabilitation post-TKA in a private hospital setting.

Methods: Single-blinded, randomised controlled trial. Participants were randomised to MAXM or SC. Participants randomised to MAXM used the skate device, accompanying iOS Application and sensors to complete MAXM exercises. The primary outcome was gains in range of motion (ROM) at 12 weeks post-TKA. Secondary outcomes included patient-reported outcomes and associated costs. Costs were assessed from a healthcare sector perspective**.**

Results: Analyses were performed when N=73 (MAXM:36/73; SC: 37/73) participants completed their 12-week follow-up. Continued participant recruitment was deemed futile given the cancellation of elective surgery at the onset of the COVID-19 pandemic in Australia. The device was safe. MAXM ROM mean gains at 12 weeks postoperative were significantly greater than SC, 43.7^0 (SD 3.9) compared to 30.9^0 (SD 1.6) (p-value = 0.005), with a mean difference of 12.9^0 (CI: 3.9, 21.8) and a quality-adjusted life-year (QALY) gain of mean 0.19 (SD 0.05) compared to 0.11 (SD 0.05), with a mean difference of 0.007 (CI: -0.007, 0.021). MAXM was cost-effective compared to SC as it was cheaper by AUD 8,316/patient (AUD 26,069/patient in sensitivity analyses) and more effective in terms of gains in ROM and QALYs.

Conclusion: This study demonstrates that MAXM is a safe, cost-effective method to improve ROM, strength and function and reduce pain post-TKA.

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Highlights

What are the new findings?

- This study presents the first study in Australia to demonstrate that the MAXM program is an effective and cost-effective method to improve ROM, strength and function and reduce pain post- total knee arthroplasty

How might it impact on clinical practice in the future?

- Our analysis supports funding MAXM within the Australian healthcare system.

Introduction

Osteoarthritis (OA) is the most common form of arthritis. It affects 7% of the global population and is responsible for 2% of total global years lived with disability (YLD) (Global Burden of Disease Collaborative Network, 2019). Between 1990 and 2019, the global prevalence of OA rose by 113% (Long et al., 2022) and is expected to rise by over 50% over the next 20 years due to increased population ageing, obesity and joint injury(Hunter et al., 2014). Knee osteoarthritis accounts for over 60% of the overall disease burden due to OA (Long et al., 2022). The global prevalence of knee osteoarthritis is estimated at 16% in individuals aged 15 and above, increasing to 23% in those over 40 years of age (Cui et al., 2020).

OA is primarily characterised by chronic joint pain and can significantly reduce an individual's quality of life. Management of OA is multifaceted, including physical, psychosocial, and mind-body approaches as well as pharmacological approaches with non-steroidal anti-inflammatory drugs (NSAIDs) as mainstay (Kolasinski et al., 2020). It is estimated that 5% of patients with OA require surgical interventions, with most patients undergoing total hip or knee arthroplasty (THA and TKA) (Ackerman et al., 2019; Maradit Kremers et al., 2015; McGrory et al., 2016; OECD, 2019). Management of OA cost the Australian health care system $3.5 billion in 2015/16, accounting for 3% of total health care expenditure (Australian Institute of Health and Welfare, 2020). Half of this expenditure is on joint replacements alone (THA and TKA), yet the incidence of these procedures in Australia is estimated to rise by 208% and 276%, respectively, by 2030 (Ackerman et al., 2019).

As primary total knee arthroplasty (TKA) procedures are increasing, so is the need for sustainable, cost-effective rehabilitation (Australian Orthopaedic Association National Joint Replacement Registry, 2017) There are no universally accepted or widely implemented

clinical guidelines to structure patient rehabilitation following TKA (Mistry et al., 2016; J. Naylor et al., 2006; Peter et al., 2014) and post-surgical rehabilitation can vary (Pozzi et al., 2013). Rehabilitative protocols are based on institution, surgeon or patient-specific preferences (J. Naylor et al., 2006; Oatis et al., 2014; Pozzi et al., 2013), resulting in inconsistent TKA therapy globally (Oatis et al., 2014; Pozzi et al., 2013). External factors such as low-value care are the primary drivers of increases in rehabilitation rates, rather than clinical indicators such as age, living status, comorbidities, or reductions in length of stay (LOS) following the acute procedure (Mahomed et al., 2008; C. Schilling et al., 2018b). Postoperative physical rehabilitation is commonly provided 1:1 in an outpatient setting. The outpatient clinic-based setting is resource-intensive and imposes a significant cost burden, yet both home/community based and hospital-based rehabilitation have demonstrated similar clinical and patient-reported outcomes (Mahomed et al., 2008; J. M. Naylor et al., 2017; Oatis et al., 2014; Chris Schilling et al., 2018a). Home-based virtual therapies present an effective, accessible, and low-cost option, notable as telehealth requirements and capabilities increased throughout 2020.(Azhari & Parsa, 2020; Karasavvidis et al., 2020). While randomised controlled trials (RCTs) have demonstrated equivalent functional outcomes when comparing inpatient or traditional outpatient rehabilitation to community- or home-based rehabilitation, greater costs are incurred with traditional methods (Fleischman et al., 2019; Prvu Bettger et al., 2020; C. Schilling et al., 2018b; Yayac et al., 2020). There is a need to investigate and introduce less costly group-based, home-based or telerehabilitation alternatives into standard practice.

This study sought to investigate the safety, efficacy, and cost-effectiveness of a home-based TKA rehabilitation program, enabling patients to autonomously track their progress in a private health setting through a range of movement (ROM) and exercise application, the MAXM Skate. The Maxm Skate package is a novel home-based rehabilitation program

comprised of a portable, lower-limb, postoperative and post-injury rehabilitation exercise device for individual use. It facilitates rehabilitation and conditioning of the lower limb through graded therapeutic exercise aimed at promoting tissue healing, remodelling and strengthening. With this device, patients perform strengthening exercises with minimal joint loading during rehabilitation (Anonymised, 2019) . The Skate device is accompanied by two sensors and a mobile app designed to provide real-time, objective data on exercise and rehabilitation progress, particularly ROM, following each home-based exercise therapy session. This sensor technology also enables the clinician to remotely monitor accurate compliance and ROM data (flexion and extension).

The primary objective of this RCT was to assess gains in range in motion (ROM) achieved by TKA patients randomised to MAXM or usual care groups at 12 weeks postoperative. Secondary objectives included comparing functional, clinical and performance-based outcome measures at multiple time points and the cost-effectiveness of MAXM.

Methods

The study protocol was approved by Bellberry Human Research Ethics Committee (Adelaide, Australia) and has been published (Anonymised, 2019). As per protocol (Anonymised, 2019), a sample size calculation based on achieving 90% power and a Type 1 error rate of 5% was chosen. The calculation determined that 110 participants (55 participants per group) would be required to detect a 10° difference in ROM between the MAXM program and SC groups three months after TKA assuming a within-group standard deviation (SD) of 16°. The clinically significant difference in ROM of 10° was estimated based on parameters described by Mockford colleagues (Mockford et al., 2008) in which the effect of a physiotherapy regimen on ROM was measured over a one-year post-TKA follow-up period. To account for

a potential 5% loss to follow-up, a total sample of 116 participants (58 per group) was to be recruited. The study recruitment period was from 18 October 2018 to 4 March 2020. In March 2020, all elective surgeries were cancelled due to the evolving COVID-19 pandemic in Australia, and participant recruitment and follow-up for the study ceased. Following an interim safety and data analysis, recruitment was deemed adequate to allow an end-point analysis of 73 participants at 12 weeks postoperatively. This also impacted the time horizon for the cost-effectiveness analysis, which was 12 months in the protocol but is now 12 weeks.

Patient recruitment and randomisation

Patients were eligible if aged 30 years and over, requiring TKA and consented to surgery. The study protocol paper reports full details of the inclusion and exclusion criteria (Anonymised, 2019) . The study site was Anonymised Private Hospital in Adelaide, Australia. Eligible patients were contacted and invited to participate. Patients who expressed an interest in the study were booked for pre-operative consent and baseline measures. Patients were screened for adverse events and medical complications. All participants provided written informed consent. Participants were randomly allocated in a 1:1 ratio to either the MAXM or SC, provided a study number, block randomised in groups of 4 and stratified by gender. The statistician generated the random sequence allocation codes using a computer-generated random number list. Information and consent occurred preoperatively with the study coordinator, as did the collection of baseline demographics and patient-reported outcome measures (PROMs) per protocol (Anonymised, 2019) . Participants also visited the blinded physiotherapist preoperatively for the collection of baseline clinical, strength and functional measures (Anonymised, 2019) .

Intervention

A single total knee prosthesis, the Advanced Coated System ACS® Fixed Bearing System (Oceania Orthopaedics Pty. Ltd.), was implanted in all study participants by a single orthopaedic surgeon. Randomised MAXM participants were required to attend an instructional session where a personal iOS device was provided if required. Recruited participants were provided with the MAXM Skate package, including safety the Skate device, rope (for assisted active motion and resistance training), 2 Bluetooth sensors, iOS device, Application (App) and accompanying booklet. The sensors and iOS App were designed to provide real-time ROM and exercise completion data (a photograph and guide of the MAXM skate device is provided in supplementary file 1). The program was divided into four stages across 12 weeks. Unblinded ward physiotherapists visited MAXM study participants to assist with setting up and using the MAXM program on day two postoperative. Post-discharge, MAXM participants were encouraged to perform and record three daily home-based sessions following the MAXM program. Data collected via the App was stored in the Google Firestore cloud database and within the iOS device. A physiotherapist visited MAXM participants at weeks 1 and 6 postoperative to ensure appropriate exercise technique and level of difficulty. Any additional outpatient physiotherapy received was recorded within the economics questionnaire at each follow-up.

Standard/Usual Care

For patients receiving standard care (SC) within the private health setting, standard inpatient physiotherapy care and the patient-specific SC options post-discharge were provided (Anonymised, 2019). Inpatient physiotherapy care included undertaking the following exercises: ankle pumps; static quadriceps; supine knee flexion; inner range quadriceps; straight leg raises; passive knee extension; seated assisted knee flexion; and active knee

extension in sitting. Once discharged from the hospital, the patient was provided four patient-specific options described in the Outpatient Standard Care Physiotherapy Protocol (Anonymised Private Hospital in Adelaide, Australia) in supplementary file 2. An independent orthopaedic surgeon performed an interim safety analysis when 73 participants reached 12 weeks post-TKA (Schiavone Panni et al., 2009).

Safety

Safety assessment was evaluated based on the management of adverse events that occurred during the clinical trial. According to the Therapeutic Goods Administration (TGA), adverse events are defined as "unintended and sometimes harmful occurrences associated with the use of a medicine, vaccine or medical device (collectively known as therapeutic goods). Adverse events include side effects to medicines and vaccines, and problems or incidents involving medical devices." (Therapeutic Goods Administration, 2022). The safety profile of MAXM was compared with adverse events data from the SC group using the test of difference between the groups.

Outcomes measuring efficacy and effectiveness

The primary outcome was the postoperative ROM achieved 12 weeks after TKA ROM was assessed preoperatively and on day 2, weeks 2, 4, 6 and 12. As confounding factors may have influenced pre-operative ROM (Vanlommel et al., 2017), the first postoperative recorded ROM was used as baseline. Obtaining ROM quickly after surgery is associated with more rapid thigh strength gains, in turn improving limb symmetry and patient return-to-function (Shelbourne et al., 2015). ROM is, therefore, a direct correlation between the MAXM Skate program compared to the SC program in terms of safety efficacy and cost-efficiency.

Secondary outcomes included PROMs, functional evaluations and associated costs. PROMs were assessed for each group preoperatively and postoperatively at six weeks, 12 weeks and 12 months. The Oxford Knee Score (OKS) (Dawson et al., 1998), Knee Injury and Osteoarthritis Outcome Score (KOOS) (Roos & Lohmander, 2003) and the Visual Analogue Scale for Pain (VASP) (Daoust et al., 2008) were used to assess knee-specific symptoms, pain and function. OKS is a 12-item questionnaire for patients having a total knee replacement. The level of satisfaction with the outpatient rehabilitation program is assessed using a 5-point Likert scale to generate a total score of 100. KOOS is a self-administered questionnaire to assess short and long-term patient-relevant outcomes following knee injury across five dimensions; pain, symptoms, activities of daily living, sport and recreation function, and knee-related quality of life. Each dimension is scored separately using a Likert scale. Scores are transformed to a 0–100 scale, where zero represents extreme knee problems, and 100 is no knee problems. Health-related quality of life (HRQoL) was assessed using the EQ-5D-5L (Herdman et al., 2011). The EQ-5D 5L is a generic multi-attribute utility HRQoL measure for individuals aged ≥ 18 years consisting of five single-item dimensions of health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (Cheung et al., 2009). When used in differentiated populations, its validity has been demonstrated in the literature (Golicki et al., 2015; Lu et al., 2016; Nolan et al., 2016). Derived from the original EuroQol 5 Dimensions 3 Levels (EQ-5D-3L) questionnaire, the EQ-5D-5L consists of five rather than three levels of impairment in each domain: no, slight, moderate, severe and extreme problems in the relevant dimension of health [14]. In line with recent NICE guidance (National Institute for Health and Care Excellence, 2017), utility values, ranging from -0.59 to 1, were estimated using a UK-specific crosswalk value set (van Hout et al., 2012). A utility score equal to 1 represents ‘full health’ states, while one less than 0 represents health states that are worse than death (Kind et al., 1999).

The Patient Acceptable Symptom State (PASS) (Tubach et al., 2005) assessed how satisfied patients were with their state. The level of satisfaction with the outpatient rehabilitation program was assessed using a 5-point Likert scale ranging from 'very unsatisfied' to 'very satisfied') at baseline, 6 and 12 weeks. Functional evaluations (isometric knee extensor strength, flexor strength and bilateral hip abduction) were assessed using a customised fixed-frame portable dynamometry hardware and software system (KangaTech, Melbourne, Australia). The maximum voluntary isometric contraction (MVIC) was tested for the hip abductors, knee extensors and knee flexors.

Data analysis

All analyses were performed using Stata version 16.1 (StataCorp, USA) and SPSS version 27.0. Patient characteristics and demographics were described using either mean and standard deviation (SD) or median (inter-quartile range) (IQR) for continuous variables and frequency (percentage) for categorical variables. As appropriate, the differences in patient characteristics between the two groups were assessed using an independent t-test, Mann-Whitney test, chi-squared test, or Fisher's exact test. Outcome variables were described using the mean (SD) and recorded at baseline (pre-operative) and 12 weeks for each intermediate time point for which data was collected. Differences between groups in the primary and each secondary outcome were assessed using linear mixed models, with fixed effects for the group, time (categorical) and a group X time interaction. The subject was included as a random intercept. For each outcome, a 2-sided hypothesis test with alpha = 0.05 as the type 1 error rate was used.

Cost-effectiveness analysis

Best practice guidelines based on the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement (Husereau et al., 2013) were followed in this economic evaluation. The analysis took a broad cost perspective that included costs borne by Australian health care (Medicare) and private costs incurred by patients (e.g., transport costs) to compare the two interventions, namely 'MAXM' versus 'standard care'. The costs and outcomes between the two groups were compared for 12 weeks from the time of randomisation to the last interim analysis follow-up. Discounting of costs and effectiveness measures was not performed because the time horizon of this study did not exceed one year (Glick et al., 2015).

Total inpatient healthcare service utilisation costs relating to admissions to hospitals, rehabilitation or nursing homes were estimated by multiplying the length of stay (days) spent in these settings by Australian diagnosis-related group (DRG) item I18B ($3,886 per day). Outpatient healthcare service utilisation costs (relating to visits for physiotherapy, rehabilitation, hydrotherapy, alternative therapies, and G.P. and nurse consultations) were calculated by multiplying the number of outpatient visits by the relevant Medical Benefits Schedule (MBS) item benefit. The cost of pharmaceuticals was estimated using Pharmaceutical Benefits Schedule (PBS) benefits data and Australian market prices. A resource use questionnaire was administered at baseline, 2, 6 and 12 weeks to estimate the number and costs of non-Medicare items (lost time due to attending hospital appointments, travelling and parking for patients and their carers). MBS items and market prices were used to cost the private cost items. The opportunity cost of time lost from work was estimated as the gross weekly rate for Australia minus tax and superannuation contributions (Australian Bureau of Statistics, 2019). An assumption was made that the opportunity cost for students, those looking after relatives or doing housework approximated the minimum wage estimated

by the Australian Fair Work Commission (Fair Work Commission, 2018). 'Leisure time' was estimated to be 40% of the mean average wages as done elsewhere (Robinson et al., 2007). We used published motoring costs to calculate private car travel costs based on the weekly costs of running a medium-sized vehicle (RACQ, 2019).

All costs are reported in Australian dollars at 2021/22-unit prices.

The relative cost-effectiveness of MAXM compared to SC was assessed. Outcomes of interest were incremental costs per unit increase in ROM and incremental cost per quality-adjusted life-year (QALY) gained at 12 weeks. QALYs were calculated using the area under the curve method and based on responses from the EQ-5D-5L. Mean (standard error) and mean differences in costs and outcomes are reported with 95% bootstrapped confidence intervals (95% CI). Bootstrapped pairs of costs and outcomes are also presented in cost-effectiveness planes (CEPs) and in cost-effectiveness acceptability curves (CEACs) (Black, 1990). CEACs show the probability of MAXM being cost-effective compared to SC at different willingness-to-pay (WTP) thresholds. For QALY-based outcomes, a WTP threshold of $50,000 per QALY gained was used. This is the implicit criterion used for assessing the cost-effectiveness of new pharmaceuticals and medical services in Australia. (Harris et al., 2008). However, no such criterion exists for ROM-based outcomes. A sensitivity analysis of the relative cost-effectiveness of MAXM compared to SC, assuming 45% of SC patients were discharged to inpatient rehabilitation in line with national estimates (C. Schilling et al., 2018b), was performed.

Results

Study sample

Figure 1 shows the flow of participants through the trial. A total of 167 patients were screened for eligibility, 73 booked for consent and randomised to receive either MAXM (n = 36) or SC (n = 37) rehabilitation. This study had a 13% loss-to-follow-up. Because the study was designed as an intention-to-treat analysis, all participants allocated to either MAXM or SC were included in data analyses despite whether they received the allocated intervention or completed the study. A total of n=33 of 36 were allocated to MAXM, and n=30 of 37 allocated to SC received the allocated intervention and remained on-study for the duration. Table 1 presents the study participants' baseline characteristics, including demographics, pre-operative clinical function and patient-reported outcome measures. Participants in the MAXM group were younger (61.7 vs 68.4 years), had a higher gait speed (1.19m/sec vs 1.04m/sec) and more were actively in employment (26% vs 12.3%) **(**Table 1). There were no significant differences between groups for any outcome measure at baseline, except for the EQ-5D-5L visual analogue scale, which was higher in the MAXM than SC (74.78±12.79 vs 65.25±19.50; p=0.031). Four participants had manual therapy for treating arthrofibrosis (describing the early reduced range of movement), also known as manipulations under anaesthesia (MUAs) (5.5%), n=3 in SC and n=1 in MAXM. Similarly, a 4% rate was found in a recent systematic review (Tibbo et al., 2019). Three deaths occurred during the study, but these were unrelated to the study or the intervention.

Safety

Forty-eight adverse events (AEs) were recorded; 43/48 were listed as ‘not related’ to treatment; 5/48 were listed as ‘possibly related’ to the use of MAXM, as they concerned the

surgical knee or leg (however, no connection to MAXM use was identified). Eight participants underwent a TKA for their contralateral knee while in the study.

Outcomes measuring efficacy and effectiveness

Table 2 shows the average adherence to MAXM rehabilitation. The average compliance of MAXM participants was 14 weeks. The average number of sessions completed per day each week was 2 in week 2 (73% of participants); 2 in week 4 (62%); 1.5 in week 6 (52%); and 1 in week 12 (38%) (Table 2). Table 3 shows the patient outcome measures results between baseline and 12 weeks. There was a significant difference in outcomes across time between groups for the Oxford 12-item score, the KOOS-12 item QOL score, the KOOS 12-item score and the KOOS-WOMAC score ($p<0.001$ for all). The KOOS-12 and the KOOS-12 QOL increased more rapidly in the first six weeks from baseline in MAXM than in SC.

Table 4 shows the Kangatech 360 strength data for pain, MVIC for hip abduction, knee extension and knee flexion. There were no significant differences between groups in MVIC or pain at 12 weeks after adjusting for baseline values in either hip abduction, knee extension or knee flexion.

Cost-effectiveness analysis

Table 5 shows the results of the costs associated with the two trial arms. At week 12, the mean per participant total costs was lower in MAXM vs SC (by $8,316 per patient). This was not statistically significant (95% CI: -$20,140 to $3,509, p-value = 0.168). The major cost drivers of the difference were admission costs in a hospital, rehabilitation setting or nursing home (lower by $9,270 per patient in MAXM (95%CI: -$21,654 to $3,114, p-value = 0.142) and outpatient costs (lower by $351 per patient in MAXM (95% CI: -$587 to -$115, p-value = 0.004)). Inpatient admission costs were lower in MAXM as Nil (0%) patients in this group

were discharged directly to a nursing home or a rehabilitation setting as opposed to 5 in SC (14%). Additionally, MAXM inpatient costs were lower, as the average LOS was close to 1 day less. Outpatient costs were higher in SC due to greater outpatient healthcare service utilisation for services such as physiotherapist and hydrotherapy visits.

Table 6 presents the mean outcomes (utility scores, ROM scores, and QALYs gained) per patient. There was a significant difference in outcomes across time between groups for the primary outcome, ROM ($p = 0.005$) and the EQ-5D-5L ($p = 0.042$). MAXM was more effective than SC in terms of EQ-5D 5L-based QALYs as it was associated with 0.007 more QALYs gained per patient (95% CI: -0.007 to 0.021, p-value = 0.343) and net gain of 12.861 units change in ROM (95% CI: 3.906 to 21.816, p-value = 0.005) (Table 6). The baseline adjusted difference for the ROM was 12.3 degrees (95% CI=4.9, 19.7, p=0.001) higher in the MAXM group than SC at week 12. In addition, there was a significant difference in ROM across time between the two groups ($p =0.004$). Therefore, MAXM dominated SC. However, there was uncertainty in these cost-effectiveness results as the cost-outcome pairs were spread in all four quadrants of the CEPs (Figures 2 and 3). MAXM had a 76% and 94% likelihood of being cost saving at 12 weeks, when the outcome was expressed in terms of QALYs (Table 6) (Figure 4) and ROM (Figure 5), respectively. MAXM was shown to have a 77% likelihood of being the cost-effective option when assessed against the implicit cost-effectiveness threshold of $50,000 per QALY used in Australia (Harris et al., 2008). In sensitivity analysis, MAXM was even cheaper (by $26,069; 95% CI: -$37,623 to -$14,515, p-value < 0.001) than SC demonstrating significant cost savings.

Discussion

With the increasing demand for TKA, further research is required to explore safe, clinically- and cost-effective alternatives for rehabilitation. This single-blinded RCT found the novel home-based approach, MAXM, safe, with improved efficacy and cost-effectiveness compared to SC following TKA. The present study rejects the null hypothesis that the MAXM program and SC are equally effective. As far as we know, this is the first and largest study that has trialled a device such as the MAXM and reported its effectiveness and cost-effectiveness.

The MAXM group demonstrates greater ROM and QALY gains over 12 weeks, with comparable clinical performance and outcome measures to SC. Previous studies have addressed the heterogeneity of SC options for rehabilitation in private hospitals in Australia (C. Schilling et al., 2018b). This study showed a degree of heterogeneity across both SC and MAXM participants who received outpatient physiotherapy or other support interventions when required. To address this limitation of participant receipt of additional care masking any potential benefit of MAXM, participant data was analysed 'as-treated', with frequency, length and type of rehabilitation captured. The MAXM group demonstrated a 12.3° more significant gain in ROM at week 12 postoperative than SC ($p<0.001$). TKA patients rarely achieve greater than 120° of flexion postoperatively, with 110° of flexion being optimal.(Bellemans et al., 2002; Fu et al., 2015; Rowe et al., 2000). Based on the awareness of requirements for daily activities, a 10° difference in ROM may delineate the ability to climb stairs or kneel down (Hefzy et al., 1998; Mulholland & Wyss, 2001; Rowe et al., 2000), which is a clinical and functional milestone for these patients.

Neuromuscular strength returned to baseline for both groups in this study, and there were no significant differences in PROMS and physical function at 12 weeks. While recent literature

has compared the efficacy of virtual- and telerehabilitation programs to SC in orthopaedics, adequate assessment of the potential impact on patient accountability, motivation, and satisfaction is lacking (Berton et al., 2020; Jansson et al., 2020; Nelson et al., 2017; Oliveira JS et al., 2020; Prvu Bettger et al., 2020). Activity trackers in older persons increased by more than 1500 steps/day when use was maintained for six months(Oliveira JS et al., 2020). In the present study, MAXM participants were equally as satisfied with their rehabilitation as SC. Anecdotal evidence from the study suggests that participants found a structured program beneficial. A telerehabilitation feasibility study in Total Joint Replacement (TJR) patients highlighted that 54.3% of 66-85 years were 'apprehensive towards technology', compared to 28.6% in the 31-65 age group. Age, social context, and access influence adaptability to technology, adherence to treatment, and outcomes (Berton et al., 2020).

Cost-effectiveness

This separation in age (MAXM average 6.69 years younger than SC) and working status (26% MAXM in employment vs 12% SC) may also contribute to the more significant costs found in MAXM vs SC in working time lost ($954). MAXM participants demonstrated lower health costs and higher QALY and ROM gains compared to SC at 12 weeks postoperatively. The mean cost savings per patient was $8,316/patient, increasing to $26,069/patient in the sensitivity analysis that used data that better reflects broader national discharge estimates. The MAXM intervention had a greater than 76% likelihood of being cost-saving and cost-effective at 12 weeks compared to SC. Overall, the MAXM intervention dominated SC when either outcome was used, suggesting MAXM is cheaper and more effective. These findings are supported by a recent systematic review of evidence on the use of smart device technology and telehealth to monitor postoperative rehabilitation (McKeon et al., 2021). This review included studies conducted between 2010 and 2020 and found that telerehabilitation

and electronic rehabilitation systems like MAXM are clinically equivalent yet cheaper alternatives to usual in-person rehabilitation. In addition, it is convenient and acceptable to the patient, as demonstrated by the high levels of patient satisfaction in the studies reviewed.

Study limitations

As this study was set in a private hospital with patients of a single surgeon, external validity and generalisability should be considered. There were comparatively low levels of direct discharge to a rehabilitation facility (MAXM 0, SC 14%) than the 2016 Australian average of 40-45% of private hospital claims data (C. Schilling et al., 2018b). These levels were low compared to the 2013-2015 average of 20.0% of public patients (Surgeons, 2018). This may indicate a potential inherent bias of patients who decided to participate. The outbreak of the COVID-19 pandemic in Australia prevented the continued recruitment of study participants, resulting in a reduced sample size (73 instead of 110). This was a significant study limitation.

Recommendation for future research

Improving understanding of the relationships between strength, functional outcomes, and patient satisfaction and determining which strength training interventions are most efficacious is required. Further studies with a larger sample size and formal strength training with objective biofeedback are recommended.

Conclusion

In this study, we found that MAXM was able to track patient ROM and provide patients with exercises across all the weeks of the study. As a result of MAXM, there was a 12.3° more significant gain in ROM at week 12 postoperative in the MAXM group than SC ($p<0.001$).

No serious adverse events related to MAXM were recorded. The MAXM device was safe for patients to use.

Our cost-effectiveness analysis found MAXM Skate, a digital health rehabilitation solution, safe and cost-effective in Australian private health care. The incremental cost per QALY gained is substantially lower than the implicit cost-effectiveness threshold. With the increasing use of technology in health, including rehabilitation following surgery, MAXM is a cost-effective alternative to in-person rehabilitation.

Patient and public involvement

We conducted a pre-study workshop with patients who had already had a total knee arthroplasty (TKA) and those about to undergo TKA. All the workshop attendees provided feedback on the feasibility and acceptability of MAXM, which was very positive.

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Figure 1. Participant flow diagram

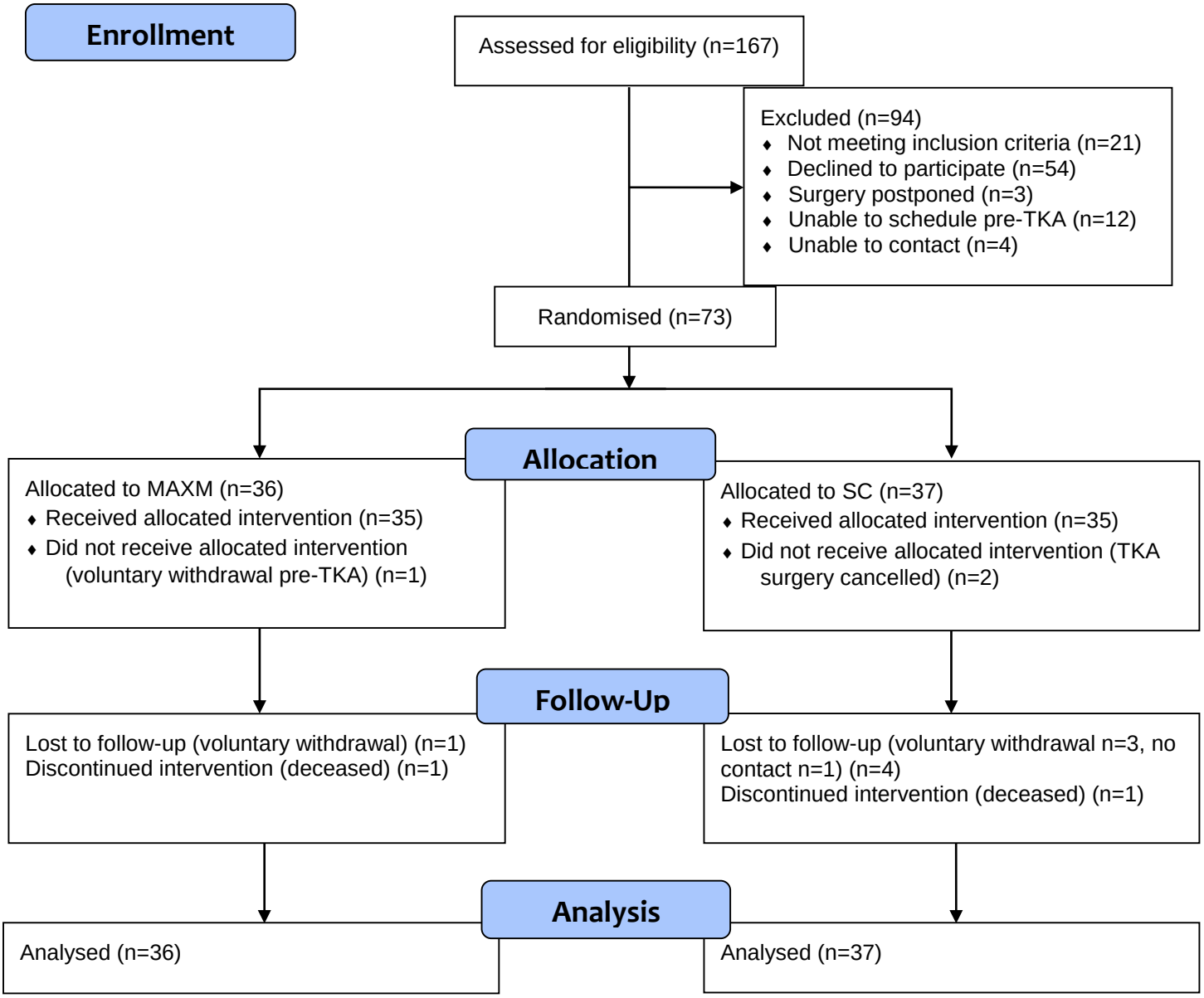

Figure 2: Cost-effectiveness plane (Quality-adjusted life years gained over 12 weeks)

Figure 2 is a cost-effectiveness plane (CEP) showing the relationship between the incremental cost and incremental outcomes (quality-adjusted life years (QALYs) gained) at 12 weeks of MAXM compared to standard treatment for total knee arthroplasty patients. It shows some uncertainty in the results as they are spread in all four quadrants.

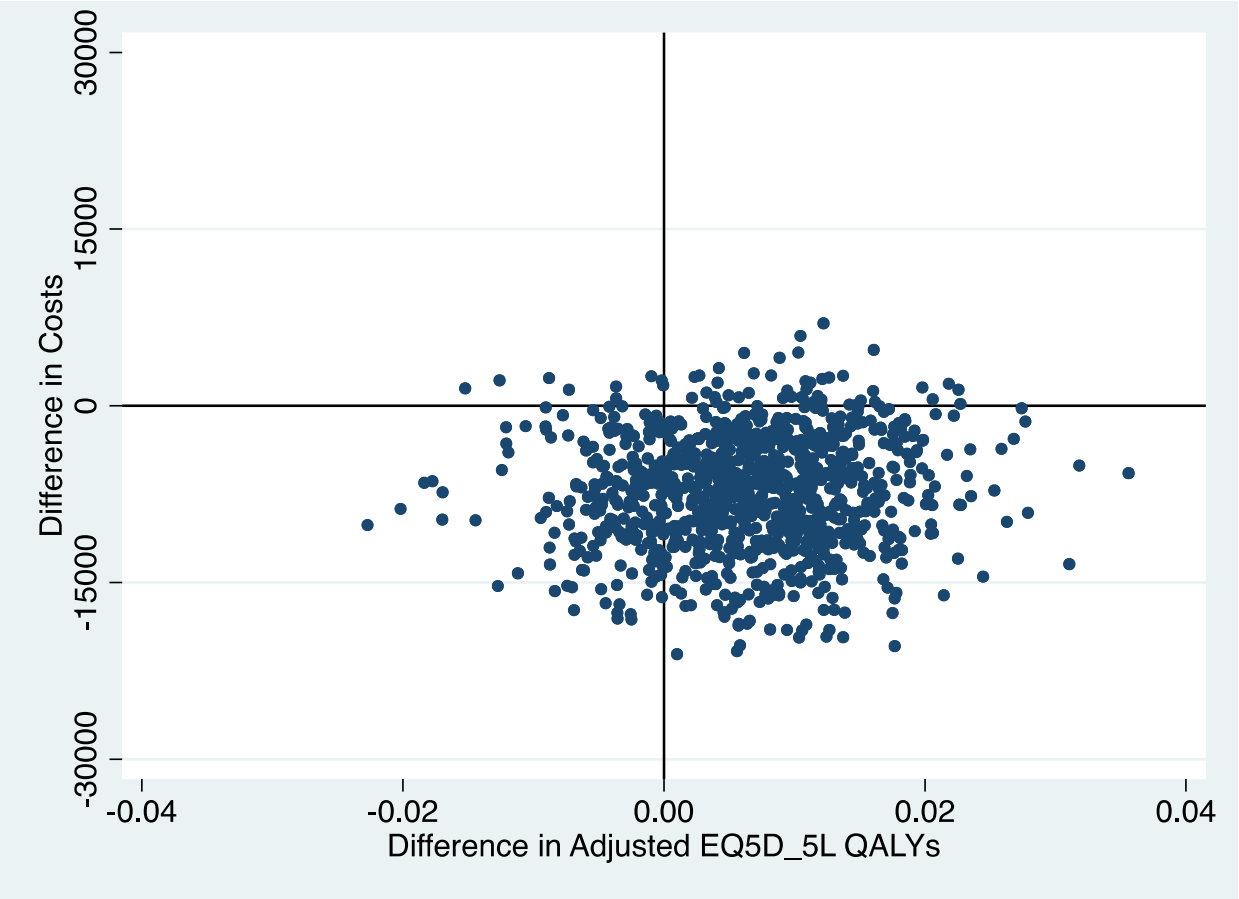

Figure 3: Cost-effectiveness plane (based on the range of motion over 12 weeks)

Figure 3 is a cost-effectiveness plane (CEP) showing the relationship between the incremental cost and incremental outcomes (range of motion gained) at 12 weeks of MAXM compared to standard treatment for total knee arthroplasty patients. It also shows some uncertainty in the results as they are spread in three of the four quadrants, i.e. northeast, south-east and south-west quadrants.

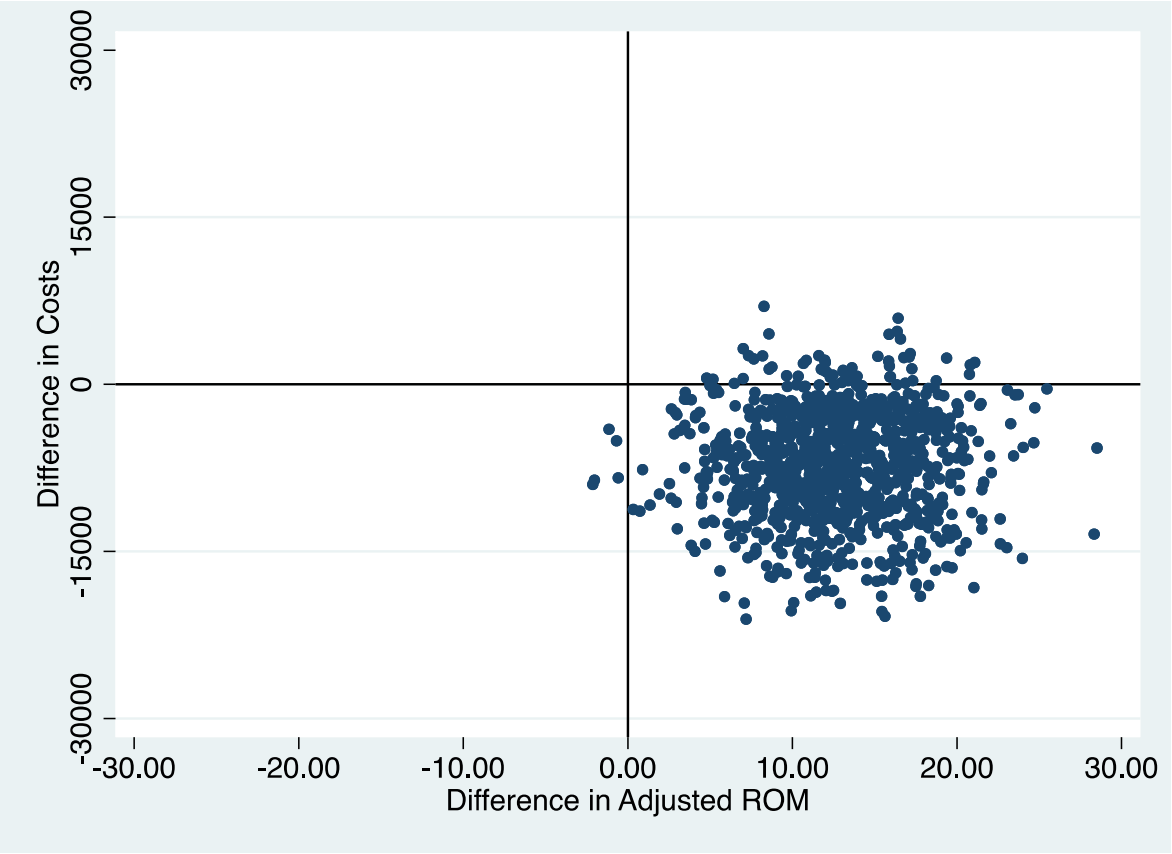

Figure 4: Cost-effectiveness acceptability curve (based on quality of life-years gained over 12 weeks)

Figure 4 depicts the cost-effectiveness acceptability curve of MAXM compared to standard care for total knee arthroplasty patients over 12 weeks. It shows that the MAXM intervention had a 76% likelihood of being cost-saving i.e. cheaper than standard care. It also shows that the probability of MAXM being cost-effective compared with standard care was about 77% if decision-makers were willing to pay at $50,000 per quality adjusted life year (QALY) gained.

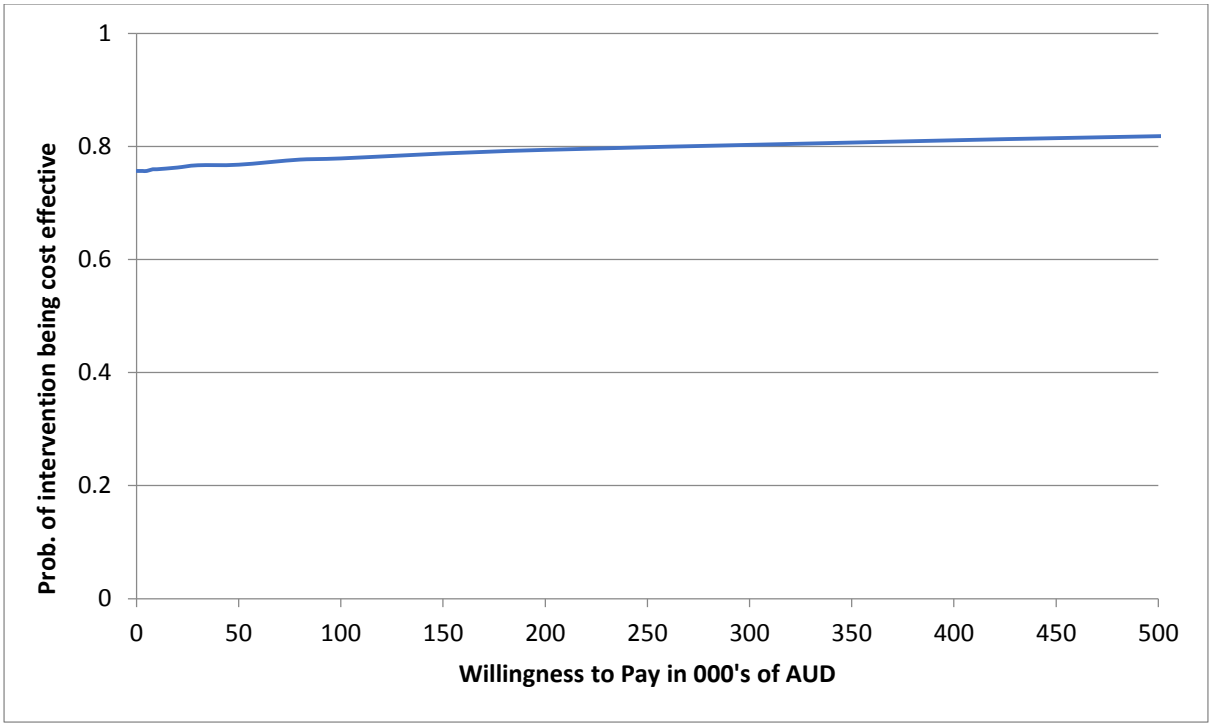

Figure 5: Cost-effectiveness acceptability curve (based on range of motion over 12 weeks)

Figure 5 depicts the cost-effectiveness acceptability curve of MAXM compared to standard care for total knee arthroplasty patients over 12 weeks. It shows that the MAXM intervention had an 94% likelihood of being cost-saving i.e. cheaper than standard care. It also shows that the probability of MAXM being cost-effective compared with standard care was about 100% if decision-makers were willing to pay at $5,000 per unit change in range of motion.

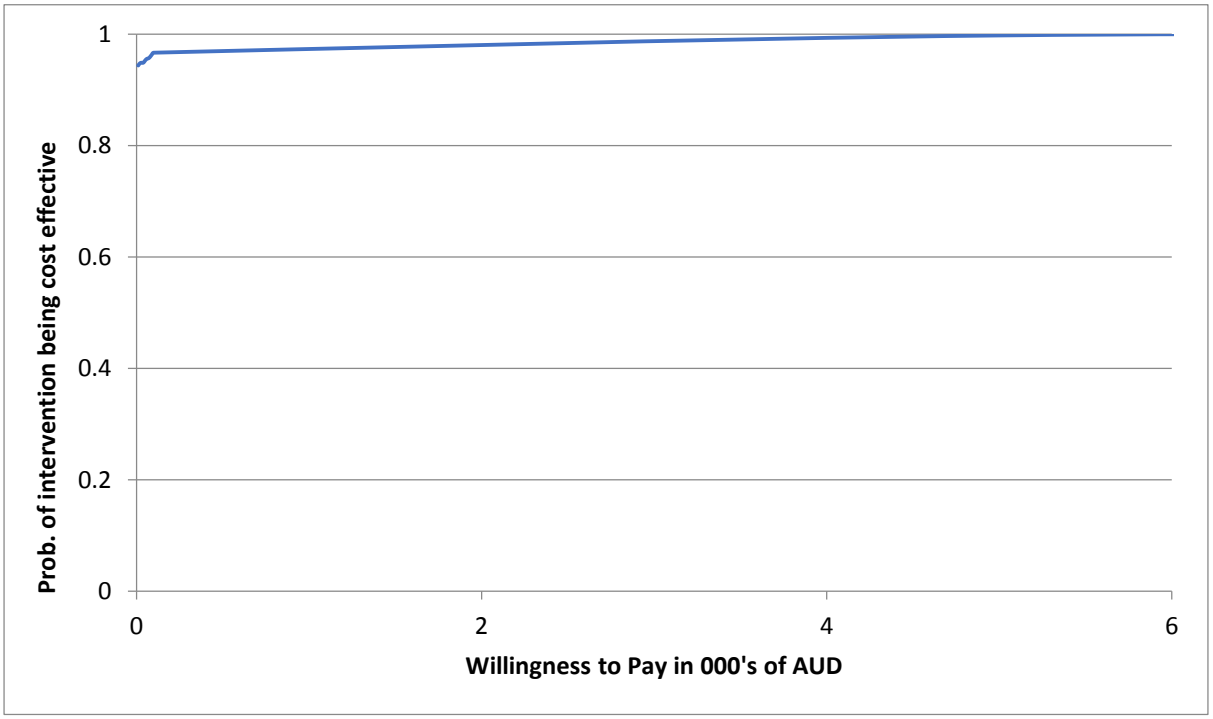

Table 1. Baseline patient characteristics, pre-operative clinical, function and patient-reported outcome measures

	All participants (n=73)	Standard Care (n=37)	MAXM (n=36)	p-value[1]
	N (%)	N (%)	N (%)	
BMI at surgery (kg/m^2)				
<25	8 (11.0)	4 (11.1)	4 (11.0)	
25-29.9	20 (27.4)	11 (29.7)	9 (25.0)	0.733
30-34.9 (obese I)	25 (34.2)	14 (37.8)	11 (30.6)	
35-39.9 (obese II)	15 (20.5)	6 (16.2)	9 (25.0)	
>40 (obese III)	4 (5.5)	1 (2.7)	3 (8.3)	
Missing	1 (1.4)	1 (2.7)		
Gender				
Male	35 (47.9)	18 (48.6)	17 (47.2)	0.903
Female	38 (52.1)	19 (51.4)	19 (52.8)	
Work status				
Retired	42 (57.5)	25 (34.2)	17 (23.3)	
Working	28 (38.4)	9 (12.3)	19 (26)	***0.029***
Volunteer work	1 (1.4)	1 (1.4)	0 (0)	
Missing	2 (2.7)	2 (5.4)		
	Mean (SD) (n=71)	**Mean (SD) (n=36)**	**Mean (SD) (n=35)**	
Age at surgery, (years)	65.1 (9.7)	68.4 (9.2)	61.7 (9.1)	***0.003***
BMI at surgery (kg/m^2)	31.2 (5.3)	30.9 (5.2)	31.6 (5.5)	0.578
Pre-operative Function				
Knee extension (degrees)	-6.6 (6.0)	-6.4 (6.4)	-6.8 (5.5)	0.776
Knee Flexion (degrees)	115.6 (10.7)	116.9 (10.1)	114.3 (11.2)	0.301
ROM (degrees)	109.0 (13.94)	110.5 (13.4)	107.5 (14.45)	0.361
VASP flexion (degrees)	3.5 (2.9)	2.7 (2.25)	4.3 (3.2)	0.870
VASP extension (degrees)	3.1 (3.0)	2.6 (2.9)	3.6 (3.0)	0.152
40m gait speed m/sec	1.12 (0.24)	1.04 (0.24)	1.19 (0.22)	***0.007***
Chair-stand reps in 30s	10.4 (3.5)	9.85 (3.75)	10.75 (3.2)	9.85
30s balance inj:uninj secs	-0.93 (8.6)	-1.6 (9.4)	-0.3 (7.8)	0.523
KOOS				
Symptoms	47.6 (17.5)	51.2 (16.7)	44.0 (17.0)	0.072
Pain	49.0 (18.4)	49.9 (18.4)	48.2 (18.5)	0.447
Function/daily living	56.4 (17.0)	55.7 (17.4)	57.0 (16.8)	0.746
Sports/recreation	15.9 (17.7)	13.4 (16.8)	18.4 (18.4)	0.229
Quality of life	27.7 (17.6)	28.2 (17.2)	27.2 (18.2)	0.810
OKS	25.1 (7.6)	24.5 (7.3)	25.6 (7.9)	0.538
EQ-5D-5L				
Mobility	2.4 (0.9)	2.47 (0.81)	2.31 (0.98)	0.449
Self-care	1.5 (0.6)	1.44 (0.61)	1.53 (0.65)	0.544
Usual activities	2.6 (0.8)	2.56 (0.77)	2.61 (0.84)	0.792
Pain/discomfort	2.9 (0.9)	2.89 (0.82)	2.89 (0.92)	1.000
Anxiety/depression	1.6 (0.8)	1.61 (0.77)	1.61 (0.90)	1.000
VAS	70.0 (17.1)	65.25 (19.50)	74.78 (12.79)	***0.031***
Satisfaction with rehab	3.24 (1.21)	3.36 (1.22)	3.11 (1.23)	0.379

Patient acceptable symptom state (PASS)	0.09 (0.28)	0.08 (0.28)	0.09 (0.28)	0.879

[1]For SC versus MAXM using t-test for continuous variables and Chi-squared or Fishers Exact for categorical variables.

BMI=Body Mass Index; ROM=Range of Movement; VASP=Visual Analogue Scale for Pain; KOOS=Knee Injury and Osteoarthritis Outcome Score; OKS=Oxford Knee Score; VAS= Visual Analogue Scale; (OKS)19 and

Table 2: Adherence to MAXM rehabilitation

Adherence to MAXM rehabilitation program (n=35)	
Weeks adhered to program	14
Average program stage reached	3
Week 2 average sessions per day	2.2 (73%)
Week 4 average sessions per day	1.9 (62%)
Week 6 average sessions per day	1.5 (52%)
Week 12 average sessions per day	1.2 (38%)

Table 3. Patient-reported outcome measures (PROMs)

	SC		MAXM		Adjusted difference (95% CI) at 12 weeks[1]	p-value[2]	p-value for interaction[3]
	n	**Mean (sd)**	**n**	**Mean (sd)**			
Oxford-12-item							
Baseline	36	24.5 (7.3)	36	25.6 (7.9)			
Week 6	32	31.1 (7.2)	33	31.5 (6.7)			
Week 12	31	33.7 (7.8)	33	35.5 (6.8)	0.41 (-3.48, 4.30)	0.837	***<0.001***
PASS							
Baseline	36	0.08 (0.28)	35	0.09 (0.28)			
Week 6	32	0.59 (0.50)	33	0.76 (0.44)			
Week 12	30	0.73 (0.45)	33	0.79 (0.42)	0.05 (-0.18, 0.27)	0.666	0.371
Satisfaction							
Baseline	36	3.36 (1.22)	35	3.14 (1.19)			
Week 6	32	4.16 (0.81)	33	4.15 (0.97)			
Week 12	30	4.00 (1.02)	33	4.30 (0.85)	0.53 (-0.06,1.13)	0.081	0.217
KOOS-12 QOL							
Baseline	36	28.1 (17.2)	36	27.1 (18.1)			
Week 6	32	44.3 (17.3)	33	48.9 (19.4)			
Week 12	31	55.7 (18.1)	33	57.6 (20.8)	3.0 (-6.5, 12.9)	0.532	***<0.001***
KOOS-12							
Baseline	36	39.6 (14.4)	36	39.6 (16.2)			
Week 6	32	57.6 (13.6)	33	59.1 (14.5)			
Week 12	31	64.8 (14.4)	33	66.9 (15.1)	1.6 (-6.4, 9.5)	0.695	***<0.001***
KOOS-WOMAC							
Baseline	36	43.5 (15.7)	36	42.4 (16.2)			
Week 6	32	26.3 (14.5)	33	26.3 (11.4)			
Week 12	31	23.3 (14.7)	33	19.2 (10.8)	-2.5 (-9.8, 4.9)	0.510	***<0.001***

Oxford 12-item = Oxford Knee Score; PASS = Patient acceptable symptoms state question, Satisfaction with rehabilitation likert scale, KOOS = Knee injury and osteoarthritis score and WOMAC = Western Ontario and McMaster Universities osteoarthritis index
[1]Baseline adjusted difference for MAXM vs SC at 12 weeks; [2]P-value for baseline adjusted difference at 12 weeks; [3]P-value for Group X time interaction between baseline and 12 weeks.

Table 4. Kangatech maximum voluntary isometric contraction (MVIC) and pain scores for hip abduction, knee extension and knee flexion

	SC		MAXM		Adjusted difference (95% CI) at 12 weeks[1]	p-value[2]	p-value for interaction[3]
	n	Mean (SD)	n	Mean (SD)			
MVIC (degrees)							
Hip Abduction							
Baseline	35	0.73 (0.28)	36	0.85 (0.43)			
Week 2	31	0.56 (0.20)	31	0.64 (0.35)			
Week 4	29	0.64 (0.24)	32	0.73 (0.34)			
Week 6	27	0.69 (0.24)	32	0.81 (0.36)			
Week 12	26	0.74 (0.25)	30	0.89 (0.36)	0.02 (-0.09, 0.13)	0.684	0.686
Knee Extension (degrees)							
Baseline	35	0.70 (0.41)	36	0.81 (0.37)			
Week 2	31	0.20 (0.10)	31	0.27 (0.30)			
Week 4	29	0.37 (0.21)	32	0.46 (0.28)			
Week 6	27	0.50 (0.25)	31	0.57 (0.29)			
Week 12	26	0.59 (0.30)	31	0.73 (0.29)	0.04 (-0.11, 0.19)	0.606	0.873
Knee Flexion (degrees)							
Baseline	48	0.47 (0.23)	40	0.45 (0.21)			
Week 2	34	0.36 (0.18)	33	0.37 (0.18)			
Week 4	29	0.45 (0.23)	32	0.44 (0.19)			
Week 6	28	0.49 (0.28)	32	0.47 (0.23)			
Week 12	26	0.51 (0.27)	32	0.58 (0.22)	-0.26 (-0.42, -0.09)	0.066	0.434
Pain							
Hip Abduction (degrees)							
Baseline	36	1.14 (1.78)	36	1.67 (2.47)			
Week 2	31	1.84 (2.28)	31	2.00 (1.88)			
Week 4	32	1.10 (1.65)	32	1.97 (2.26)			
Week 6	32	0.78 (1.34)	32	1.22 (1.98)			
Week 12	30	0.42 90.76)	30	0.87 (1.57)	0.09 (-0.95, 1.13)	0.862	0.791
Knee Extension (degrees)							
Baseline	35	2.66 (2.46)	36	3.08 (2.81)			
Week 2	31	4.55 (2.19)	31	5.71 (2.56)			
Week 4	29	3.76 (2.01)	32	4.28 (2.61)			
Week 6	27	3.07 (2.27)	31	3.74 (2.73)			
Week 12	26	1.69 (1.93)	31	1.94 (1.95)	-0.13 (-1.54, 1.27)	0.851	0.782
Knee Flexion (degrees)							
Baseline	48	1.73 (1.84)	40	2.75 (2.84)			
Week 2	34	2.50 (2.25)	33	2.61 (1.98)			
Week 4	29	1.66 (1.67)	32	2.53 (2.12)			
Week 6	28	1.89 (2.23)	32	1.72 (2.02)			
Week 12	27	1.23 (1.77)	32	1.34 (1.96)	-0.37 (-1.45, 0.71)	0.497	0.294

[1]Baseline adjusted difference for MAXM vs SC at 12 weeks; [2]p-value for baseline adjusted difference at 12 weeks; [3]p-value for Group X time interaction between baseline and 12 weeks. MVIC=Maximum Voluntary Isometric Contraction

Table 5. Mean healthcare utilisation and costs per patient (at 12 weeks)

Variable	n	Standard Care Mean (SE)	n	MAXM Mean (SE)	Difference (Bootstrapped 95% CI)	p-value
Health care service utilisation						
A. In-patient healthcare service utilisation - In-patient hospital, Rehabilitation or nursing home visits						
In-patient index admissions at Flinders Private Hospital (Length of stay – LOS)	35	4.943 (0.583)	35	4.057 (0.254)	-0.886 (-2.094, 0.323)	0.151
In-patient hospital admissions for Manipulation Under Anaesthesia	35	0.086 (0.030)	35	0.029 (0.037)	-0.057 (-0.152, 0.037)	0.235
In-patient hospital admissions for knee/fall-related pain	35	0.057 (0.098)	35	0.086 (0.082)	0.029 (-0.313, 0.370)	0.87
Direct discharges to rehabilitation or nursing home after index admission	35	1.200 (0.525)	35	0.000 (0.000)	-1.200 (-2.311, -0.089)	0.034
Total In-patient healthcare service utilisation	***35***	***6.286 (1.360)***	***35***	***4.171 (0.207)***	***-2.114 (-4.939, 0.710)***	***0.142***
B. Out-patient healthcare service utilisation						
Physiotherapist Home Visits	36	3.972 (0.540)	36	0.639 (0.329)	-3.333 (-5.315, -1.352)	0.001
Out-patient Physiotherapy	36	4.389 (0.495)	36	2.417 (0.426)	-1.972 (-3.816, -0.128)	0.036
Day Rehabilitation	36	0.250 (0.144)	36	0.250 (0.248)	0.000 (-0.365, 0.365)	1
Out-patient Hydrotherapy	36	2.250 (0.416)	36	0.972 (0.359)	-1.278 (-1.950, -0.606)	0
General Practitioner Appointments	36	2.583 (0.159)	36	1.889 (0.469)	-0.694 (-1.890, 0.502)	0.255
Nurse Appointments	36	0.889 (0.152)	36	0.667 (0.083)	-0.222 (-0.758, 0.313)	0.416
Alternative Therapist Appointments	36	1.056 (0.164)	36	1.250 (0.369)	0.194 (-0.734, 1.122)	0.681
C. Patient indirect input						
Total distance travelled (kilometres) covered when attending appointments	36	54.544 (4.570)	36	43.933 (6.905)	-10.611 (-41.386, 20.163)	0.499
Number of hours of work lost by patient while attending appointment	36	174.672 (11.374)	36	234.622 (30.843)	59.950 (9.604, 110.295)	0.02

Variable	n	Standard Care Mean (SE)	n	MAXM Mean (SE)	Difference (Bootstrapped 95% CI)	p-value
Number of hours of work lost by carer accompanying patient for appointment	36	0.472 (0.282)	36	2.906 (1.325)	2.433 (0.066, 4.800)	0.044
Costs						
D. In-patient healthcare service utilisation Costs - In-patient hospital, Rehabilitation, or nursing home						
In-patient index hospital admissions (visits) at Flinders Private Hospital ($)	35	21,672 (2,555)	35	17,788 (1,112)	-3,883 (-9,182, 1,415)	0.151
In-patient hospital admissions for Manipulation Under Anaesthesia ($)	35	376 (131)	35	125 (160)	-251 (-664, 163)	0.235
In-patient hospital admissions for knee/fall-related pain ($)	35	251 (428)	35	376 (361)	125 (-1,373, 1,623)	0.87
Direct discharge to rehabilitation or nursing home after index admission ($)	35	5,261 (2,300)	35	0 (0)	-5,261 (-10,133, -390)	0.034
Total In-patient healthcare service utilisation costs	***35***	***27,559 (5,965)***	***35***	***18,289 (907)***	***-9,270 (-21,654, 3,114)***	***0.142***
E. Out-patient healthcare service utilisation costs ($)						
Physiotherapist Home Visits ($)	36	121 (13)	36	26 (15)	-96 (-151, -41)	0.001
Out-patient Physiotherapy ($)[a]	36	101 (15)	36	62 (12)	-39 (-94, 16)	0.168
Day Rehabilitation ($)	36	60 (36)	36	75 (73)	16 (-85, 117)	0.761
Out-patient Hydrotherapy ($)	36	264 (42)	36	92 (34)	-172 (-225, -119)	<0.001
General Practitioner Appointments ($)	36	94 (6)	36	69 (17)	-25 (-69, 18)	0.255
Nurse Appointments ($)	36	32 (6)	36	24 (3)	-8 (-27, 11)	0.416
Alternative Therapist Appointments ($)	36	91 (39)	36	64 (15)	-27 (-157, 103)	0.683

Variable	n	Standard Care Mean (SE)	n	MAXM Mean (SE)	Difference (Bootstrapped 95% CI)	p-value
Total Out-patient healthcare service utilisation costs	***36***	***763 (95)***	***36***	***411 (79)***	***-351 (-587, -115)***	***0.004***
F. Drug costs ($)						
Drug costs	***35***	***117 (3)***	***35***	***105 (14)***	***-11 (-41, 19)***	***0.464***
G. Private costs ($)						
Transport to, and parking costs while attending, appointment ($)	36	37 (3)	36	30 (5)	-7 (-28, 14)	0.512
Time lost by patient while attending appointment ($)	36	3,348 (218)	36	4,497 (591)	1,149 (184, 2,114)	0.02
Time lost by carer accompanying patient for appointment ($)	36	22 (16)	36	168 (97)	146 (1, 291)	0.048
Over the counter medication ($)	35	57 (4)	35	84 (32)	27 (-40, 94)	0.431
Gap payment for equipment, supplies etc ($)	36	82 (16)	36	58 (10)	-25 (-79, 30)	<0.001
Total Private costs	***35***	***3,646 (579)***	***35***	***4,972 (448)***	***1,327 (-685, 3,338)***	***0.196***
Total Costs (Medicare and Private costs ($)	**35**	**32,106 (5,936)**	**35**	**23,790 (643)**	**-8,316 (-20,140, 3,509)**	**0.168**

Table 6. Mean outcomes (utility scores, ROM scores and QALYs gained) per patient

Variable	n	MAXM Mean (Standard error)	n	Standard Care Mean (Standard error)	Difference (Bootstrapped 95% CI)	p-value
EQ-5D-5L Scores						
EQ5D-5L Scores at baseline	36	0.571 (0.039)	36	0.579 (0.019)	-0.008 (-0.116, 0.100)	0.884
EQ5D-5L Scores at 12 weeks	34	0.763 (0.024)	32	0.693 (0.036)	0.070 (0.003, 0.138)	***0.042***
EQ-5D-5L utility score gains (baseline to 12 weeks)						
EQ5D-5L Scores	34	0.192 (0.046)	32	0.114 (0.046)	0.078 (-0.034, 0.190)	0.171
EQ-5D-5L QALYs gains (baseline to 12 weeks)						
Adjusted QALY gains	34	0.159 (0.004)	30	0.152 (0.005)	0.007 (-0.007, 0.021)	0.343
ROM (Degrees)						
ROM Scores at baseline	35	61.829 (3.336)	34	72.685 (1.320)	-10.856 (-19.236, -2.477)	***0.011***
ROM Scores at 12 weeks	32	105.558 (1.743)	28	103.554 (2.453)	2.005 (-5.782, 9.792)	0.614
ROM gains (baseline to 12 weeks)						
ROM Scores	32	43.730 (3.907)	27	30.869 (1.588)	12.861 (3.906, 21.816)	***0.005***

ROM=Range of Movement; QALYs = Quality-Adjusted Life Years