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Patient outcomes using Wii-enhanced rehabilitation after total knee replacement – The TKR-POWER study

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ABSTRACT

Background: Home-based rehabilitation following total knee replacement surgery can be as effective as clinic-based or in-patient rehabilitation. The use of the Nintendo Wii has been postulated as a novel rehabilitation tool that adds an additional focus on balance and proprioception into the recovery protocol. The aim of the proposed clinical trial is to investigate the effectiveness of this novel rehabilitation tool, used at home for three months after total knee replacement surgery and to assess any lasting improvements in functional outcome at one year.
Methods/Design: This will be a randomised controlled trial of 128 patients undergoing primary total knee replacement. The participants will be recruited preoperatively from three surgeons at a single centre. There will be no change to the usual care provided until 6 weeks after the operation. Then participants will be randomised to either the Wii-Fit group or usual rehabilitative care group. Outcomes will be assessed preoperatively, a 6-week post surgery baseline and then at 18 weeks, 6 months and 1 year. The primary outcome is the change in self-reported WOMAC total score from week 6 to 18 weeks. Secondary outcomes include objective measures of strength, function and satisfaction scores.
Discussion: The results of this clinical trial will be directly relevant for implementation into clinical practice. If beneficial, this affordable technology could be used by many patients to rehabilitate at home. Not only could it optimize the outcomes from their total knee replacement surgery but decrease the need for clinic-based or outpatient therapy for the majority.
Trial Registration: (ACTRN12611000291987).

1. Background

The use of video game systems in the rehabilitation of patients has been increasing in the medical and allied health community in the last decade. These gaming systems have been shown to be more fun than conventional exercise in a rehabilitation setting [1–3]. The Nintendo Wii™ and Wii-Fit™ (Nintendo of America, Redmond, WA, USA) is a popular, motion controlled gaming system used across a broad age range and available to the general public. It is easy to use and can deliver a varied exercise routine, with a focus on balance. The Wii has been used to rehabilitate patients with neurological injuries [4–7] but there have been few quality studies describing the use of the Wii to rehabilitate orthopaedic patients [8,9]. A feasibility study using the Wii as an adjunct to physiotherapy concluded that it has potential for patients following TKR, but the study was underpowered to find a difference. The study also used the

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Wii in the physiotherapy rooms during a supervised session, not as a home-based device [9].

The number of total knee replacements (TKR) surgeries performed annually is increasing across the developed world. The Australian joint registry has recorded over 40,000 TKRs performed each year in Australia, increasing by approximately 6000 each year. [10] There is good evidence that a TKR leads to the relief of pain but studies consistently report that 20% of patients remain dissatisfied after their surgery [11–14].

Health related quality of life scores, especially physical function, remain lower after TKR surgery than an age-matched population, despite significant improvements from their preoperative levels [12,15–19]. Functional deficits remain in most patients at one year after TKR surgery and beyond [20–23]. It is not known if these deficits are the inevitable result of disease and surgery or if they can be improved with targeted rehabilitation. The WOMAC index is a validated subjective outcome measure for TKR arthroplasty patients and includes pain, stiffness and functional subscales making it ideal for a rehabilitation study.

Home-based exercise can be as effective as physiotherapist led rehabilitation [24–29]. Applying this gaming technology as a rehabilitation tool at home is likely to be of equal benefit to a supervised setting and may be more cost-effective.

Delaying the intensive phase of rehabilitation until six weeks post operation has been shown to be effective in the short term [30]. This could be due to swelling, pain and even anaemia delaying exercise at an intensity that would contribute significantly to muscle strength [31].

The aim of this proposed clinical trial is to investigate the effectiveness of using the Nintendo Wii-Fit for rehabilitation at home after a primary TKR. It is to be used daily for 3 months, starting at six weeks post surgery with the primary outcome being change in WOMAC total score from the six week baseline to 18 weeks and 1 year. We hypothesise that it will improve subjective and objective functional outcomes and increase adherence to recommended rehabilitation programs when compared to usual care in patients following unilateral primary total knee replacement surgery.

2. Methods / Design

The TKR-POWER study (Total Knee Replacement –Patient Outcomes Using Wii-Enhanced Rehabilitation) is a randomized controlled trial that will be conducted from one research Institute in Australia studying patients operated on at two large private hospitals by three surgeons. Participants will be required to provide written informed consent prior to starting the study. Ethics approval was obtained from the Northern Sydney Human Ethics Review Committee (HREC) and the University of Sydney HREC using the National Ethics Application form http://www.neaf.gov.au/ The TKR-POWER study has been registered at the Australian and New Zealand Clinical Trials Registry. (ACTRN12611000291987).

Following a routine decision made by the orthopaedic surgeon and patient to undergo total knee replacement surgery all potential participants will be invited to participate and undergo initial screening for eligibility prior to signing the informed consent and baseline assessments at the rooms of the three operating surgeons. Inclusion criteria are 1) Primary unilateral or bilateral TKR, 2) English speaking. Exclusion criteria are 1) Inability to return for all extra follow up visits 2) Medical conditions severely affecting their balance.

There will be no change to the usual medication or rehabilitative care during the peri-operative inpatient or post-operative period up until 6 weeks after the operation. While this may be a confounder, the groups are randomised. The study population will all have private health insurance giving them access to rehabilitation in the first 6 weeks. Previous studies that have tried to change the rehabilitation in this period have struggled with recruitment due to patient choice on early rehabilitation. The quantity and location of rehabilitation in the first 6 weeks will be recorded and analysed as a covariate.

At the 6-week visit, patients will be randomized into the Wii group or the usual rehabilitative care specific to the treating surgeon (Control group). Randomization schedules will be generated a priori using a computer generated random number sequence by an independent researcher with no participant contact. Separate randomization schedules will be made for unilateral and bilateral TKRs. Allocations will be sealed in opaque and consecutively numbered envelopes with a clear audit trail.

The control group will have their exercises demonstrated in the research institute. The Wii group will have a single home visit to ensure correct set-up of the Wii and demonstration of the exercises. Both groups will have the lead investigators telephone number for any queries on exercises.

2.1. Interventions

2.1.1. Control group

Participants will be given written descriptions and diagrams of the exercises to perform at home between 6 weeks and 18 weeks post-op. They will be given a diary to record their daily exercise. The diary will also serve as the instructions for when to perform the different exercises.

The exercises were taken from the standard rehabilitative exercise sheet given to patients by one of the major hospitals in which the majority of the participants had surgery and early rehabilitation. The advice will be to perform exercises such as squats, step-ups and calf raises for a total of 30 minutes each day (see Appendix 1). The prescription will be for 3 sets of 10 repetitions of each exercise.

2.1.2. Wii Group

Participants will receive the same exercise sheet and diary as the control group and will be asked to record any of these standard rehabilitative exercises that they perform.

Participants will also receive a second set of diaries that detail three stages of Wii exercises that increased in difficulty every 4 weeks. They will also be given a Wii console and balance board with Wii-Fit software to take home. The Wii-Fit software splits its exercises into yoga, strength training, aerobic and balance categories. The software explains the exercises and gives feedback in real time. They will be asked to perform a total of 30 minutes each day, using the Wii preferentially over the routine exercises (See Appendix 2). The prescription will be for 1 set of each exercise as the Wii-Fit automatically builds in repetitions to each set. There will be three Wii diaries corresponding to three phases of four weeks each. In each