**RESEARCH PROTOCOL**

**[Wolper Jewish Hospital]**

**PILOT TRIAL PROTOCOL**

**The acceptability and accessibility of magnetic walking aids when used in hospital: a randomised trial**

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| --- | --- | --- | --- |
| VERSION NO. | 3 | DATE | 10/08/2021 |
| INVESTIGATIONAL PRODUCT NAME | Magnetic Walking Aid (PRAGNETICS Pty Ltd) | | |
| TRIAL PHASE | Phase 1 | | |
| SPONSOR(S),  Address | Alexander Roberts  Wolper Jewish Hospital: 8 Trelawney St, Woollahra NSW 2025 | | |
| PRINCIPAL INVESTIGATOR  name and contact information | Alex Roberts Mob: 0435754766 | | |
| MEDICAL MONITOR  name and contact information | N/A | | |
| COORDINATING CENTER  (if applicable) | N/A | | |

**APPROVED BY:**

|  |  |
| --- | --- |
| Alexander Roberts | 10/8/21 |
| *Principle Investigator or Sponsor Signature and Title* | *Date* |

|  |
| --- |
| Wolper Jewish Hospital 8 Trelawney St, Woollahra NSW 2025 |
| *SITE* |

# PROTOCOL AGREEMENT

I have read and understand the protocol below. In my capacity as Investigator, my duties include making sure of the safety of the study participants enrolled by supervising them and providing [Alex Roberts/ Wolper Jewish Hospital] with complete and timely information. This information will be provided as outlined in this study protocol. All the information relating to this study will be held in strict confidence and these confidentiality requirements apply to all staff at this study site or involved with this study. I agree to maintain the procedures required to perform this study in accordance with Good Clinical Practice principles and to abide by the terms of this protocol.

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| --- | --- | --- | --- |
| PROTOCOL NO. | 3 | PROTOCOL DATE | 10/08/2021 |
| PROTOCOL TITLE | The acceptability and accessibility of magnetic walking aids when used in hospital: a randomised trial | | |

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| --- | --- |
| Alexander Roberts | 10/08/21 |
| *Investigator Signature* | *Date* |

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| --- |
| Mr Alexander Roberts |
| *Name and Title (Print)* |

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# PROTOCOL SYNOPSIS

|  |  |
| --- | --- |
| PROJECT TITLE | The acceptability and accessibility of magnetic walking aids when used in hospital: a randomised trial |
| SPONSOR(S) | Alexander Roberts  Wolper Jewish Hospital: 8 Trelawney St, Woollahra NSW 2025 |
| LOCATION | Level 1 Rehab ward |
| RATIONALE | Patients require walking aids post joint replacement. Failure to use the aid, or difficulty accessing the aid, can lead to adverse outcomes such as inappropriate weight bearing, loss of balance and falls. This study investigates whether a Magnetic walking aid (MWA) enables simpler, safer and more secure access to a mobility assistive device and increases walking aid acceptability within the hospital after joint replacement, compared to standard walking aids (SWA), i.e. the normal standard of care (SOC). |
| STUDY DESIGN | Hospital-based parallel randomised trial. |
| PRIMARY OBJECTIVE | Assess acceptability and accessibility of magnetic walking aids (MWA) compared to standard walking aids (SWA) in patients following joint replacement. |
| SECONDARY OBJECTIVE(S) | Determine if the MWA, compared to a standard walking aid reduces:   * Poor compliance to mobility aids use * The number of times a hospital staff member is called to retrieve a fallen walking aid * The number of occasions the walking aid comes to rest on the floor accidentally * The number of occasions patients with posterior hip replacement break their post-op protocol by retrieving a walking aid from the ground   Assess the acceptability of MWAs to staff caring for inpatients following joint replacement.  Provide falls data to establish an effect size for fall rates to be used to inform a future large-scale trial. |
| NUMBER OF SUBJECTS | Total = 40 (n = 20 MWA; n = 20 SOC aid). |
| SUBJECT SELECTION CRITERIA | Inpatient requiring a walking stick or elbow crutch to mobilize.  Total hip or total knee replacement within the last 4 weeks.  Exclude cognitively impaired, nil stroke, nil Parkinson’s Disease. |
| PRODUCTAND ROUTE OF ADMINISTRATION | The product is an MWA which will be able to adhere to magnetic wall mounts placed standardized locations in the bathroom, bedside and beside the plinth on ‘Level 2 gym.’  Participants will be trained in the use of the MWA and the magnetic attachments will be administrated by trained Wolper staff members. |
| (CONTROL) PRODUCT AND ROUTE OF ADMINISTRATION | Standard walking aids.  Participants will be trained in the use of the standard walking aid by trained Wolper staff members. |
| DURATION OF SUBJECT PARTICIPATION AND STUDY DURATION | |
| SCREENING | Screening process prior to the patient arriving to Wolper Jewish Hospital is completed by the Nursing Unit Manager (NUM) (Marcelle Segal) on ‘Level 1.’ Prior to their admission into the hospital, potential eligibility will be assessed. This includes: past medical history, social history, age, admission reason, current mobility status. |
| TREATMENT | All participants will undergo the usual inpatient treatment and care. Participants will be randomized to receive either the MWA or the SOC walking aid. Two Magnetic mounts for the MWAs will be placed in standardized positions for each participants’ bedside, bathroom by the toilet and shower, and between each physiotherapy treatment bed on ‘Level 2 gym’ at Wolper. Participants will keep a record of the number of times their walking aid comes to rest on the floor each day. |
| FOLLOW-UP | Either after 8 days of walking aid use, when the participant no longer needs the aid, or on discharge (whichever happens first), each patient will fill out a short (10 minute) survey regarding their experience with the MWA or the SOC walking aid. At the conclusion of the trial, staff involved in the care of participants will be asked to complete a short survey (5 minutes) about their experience of caring for people using the MWAs. |

# Study Team and Site(s)

**Team: Alex Roberts, Lucy McCarthy, Jessica Trim, Alex Smith, Marcelle Segal, Cody Kane, Dr Malcom Bowman,   
Dr Tracy Murrant and Natalie Allen (University of Sydney research mentor)**

**Location Wolper Jewish Hospital**

**Contact: Alex Roberts: 0435754766**

**Due to involvement in the design and sales of the MWAs, the principal investigator (Alex Roberts) will not be involved in the recruitment, intervention, or data collection.**

# Study Objectives

## Primary Objective

## **Assess the acceptability and accessibility of MWAs compared to standard walking aids in patients following joint replacement.**

## Secondary Objective(s)

**Determine if the MWA, compared to a standard walking aid, reduces:**

* **Poor compliance to mobility aids use**
* **The number of times a hospital staff member is called to retrieve a fallen walking aid**
* **The number of occasions the walking aid comes to rest on the floor accidentally**
* **The number of occasions patients with posterior hip replacement break their post-op protocol by retrieving a walking aid from the ground**

**Assess the acceptability of MWAs to staff caring for inpatients following joint replacement.**

**Provide falls data to establish an effect size for fall rates to be used to inform a future large-scale trial.**

# Background

**According to incident management data collect from Wolper Hospital over the last quarter (1 October – 31 December of 2020) nine falls occurred in the hospital. Of these falls, two resulted in an admission to St Vincent’s Hospital Emergency Department. Both of these falls were due to walking aid misuse and therefore germane to the objective stated in this research study.**

**The first fall was due to a patient bending down to ‘pick something off the floor’ resulting in a hip dislocation on 16/11/2020.**

**The second fall was due to a walking aid not being accessible in the patient’s room leading to a head injury on 14/12/2020.**

**Walking aids are an essential treatment for an inpatient’s hospital stay. It allows the patient, who would not otherwise be able, to mobilise. Safer use of walking aids could lead to earlier discharge from the hospital system. Walking aids also help to prevent falls in high-risk patients**1–4**, with falls being a burden on the healthcare system.**5

**Despite their benefits, walking aids are rendered useless if the patient does not adhere to using the device in the prescribed manner. Adherence to walking aid use within the hospital and community-based settings are difficult for health professionals to monitor.**6,7 **Research has demonstrated that walking aid non-compliance in the community may lead to increased falls and increased injurious falls, including injuries requiring surgery.**7 **Inaccessibility of the walking aid was cited as a reason for non-use.7 Moreover, severe injuries such as pelvic fractures, as a result of falls from a standing position in patients over 65 years, have a mortality rate of 41% after 3 years.**8

**In Australia, walking aid holders of any kind (for example the frog holder aid**9**), magnetic or otherwise, are not widely used. We propose that adequate training and prescription of a magnetic walking aid** **during a given patient’s admission will reduce risk factors relating to in-hospital falls in a safe and cost-effective way.**

1. Study Design

**Type: Hospital-based parallel randomized trial**

**Stage: Pilot study**

**Location: Wolper Jewish Hospital**

**Period of enrollment: Average of ~8 days hospital admission length**

**Stages of the study:**

* **Staff involved in the care of potential participants will be invited to participate and to provide their written informed consent**
* **Initial assessment of potential patient participants based on St Vincent handover/ referral to NUM, and assessment against inclusion criteria**
* **Run in period: until patients’ mobility is assessed by adm****itting physiotherapist**
* **Pre-randomisation: Obtain written informed consent from patient participants, explain study in basic terms, give tracking chart of walking aid drops**
* **Background information including age, gender and type of surgery will be collected for each patient participant**
* **Randomisation: To begin their participation in the trial, an individual external from the trial (Darshan Nair) selects 1 envelope at random from 40 concealed black envelopes. Inside each envelop is either ‘MWA’ (20 envelopes) or ‘SOC’ (20 envelopes). This will determine which group the participant is allocated to.**
* **Treatment phase: participants either use SOC or MWA during hospital admission and keep a daily record of the number of times their walking aid is dropped**
* **End-of-phase assessment: follow up questionnaire given to participants regarding perception of either MWA or SOC**
* **Trial exit: on discharge, all participants will default back to SOC unless the participant requests to purchase the MWA**
* **All hard copies of paperwork will be stored in Cody Kane’s ‘Level 2’ office in a locked filing cabinet, and accessed only by the named researchers. Electronic data will be stored in the incident management database.**
* **After all 40 participants have completed the trial, all staff who were involved in the trial and consented before the trial started will complete a staff follow-up questionnaire.**

**Primary outcomes:**

* **Acceptability of the MWA compared to the standard walking aid, as assessed with a patient questionnaire and staff survey (see attached)**
* **Accessibility of the MWA compared to the standard walking aid, as assessed with a patient questionnaire and the ‘number of times walking aid dropped’ form (see attached)**

**Secondary outcomes:**

* **Adherence to mobility aids use will be assessed with patient and staff questionnaires**
* **The number of times a hospital staff member is called to retrieve a fallen walking aid will be assessed with patient and staff questionnaires (see attached)**
* **The number of occasions the walking aid comes to rest on the floor accidentally will be assessed with the ‘number of times walking aid dropped’ form (see attached)**
* **The number of occasions patients with posterior hip replacement break their post-op protocol by retrieving a walking aid from the ground will be evaluated by looking at the patient questionnaire and the ‘number of times walking aid dropped’ form for this subgroup**
* **The acceptability of the MWAs to staff participants caring for inpatients following joint replacement will be evaluated with a staff questionnaire (see attached)**
* **Any falls in participating patients will be recorded, along with the circumstances of the fall. Falls data will be used to establish an effect size for fall rates which could then be used to inform a future large-scale trial.**

5. Subject Inclusion and Exclusion Criteria

**Inclusion Criteria (patients)**

* **Requires a walking aid to mobilize on admission to Wolper Jewish Hospital rehabilitation ward**
* **Post total knee or hip replacement surgery within the last 4 weeks**

**Exclusion Criteria (patients)**

* **Cognitively impaired based on past medical history on admission**
* **Not mobilizing with either a walking stick, elbow crutch or axillary crutch at their previous hospital**
* **Does not have the strength to pull the magnetic walking aid off the wall**

**Inclusion criteria (staff)**

* **Staff directly caring for inpatients participating in the research project**

# 6. Study Enrolment Procedures

**Patient participants:**

1. **The patient is screened by the NUM of Wolper Jewish Hospital on the Rehab Ward to assess suitability for the trial**
2. **The patient is admitted to Wolper and asked by the NUM if they would like to participate in a trial:** **’A falls prevention and mobility aid usage trial’**
3. **Patient provided with a Participant Information Statement and the trial is verbally explained. The patient is given the opportunity to ask questions. The patient is informed that they can decline to participate or withdraw from the study at any time without providing an explanation.**
4. **Patients who want to participate fill out informed consent**
5. **The patients are then randomly allocated to either the MWA or SOC for the course of their hospital stay**
6. **A tutorial on how to use the MWA and SOC aids are given. The participant is to then sign a form acknowledging they have received a tutorial on how to use the walking aid and potential risks.**

**Staff participants:**

1. **Eligible staff will be provided with a Participant Information Statement and given an opportunity to ask questions about the study. They will be informed that they do not have to participate and can withdraw at any time.**
2. **Staff who would like to participate will provide written informed consent**

# Study Intervention, Duration, and Route of Administration

**6x walking sticks and 6x pairs of elbow crutches are to be put aside for trialing (only in the ‘Level 2 Physiotherapy Storage Room’).**

**Walking aids are to be pre-fitted with the magnetic component prior to trial use.**

**Standard Hygiene measures are to be used between participant use of the magnetic walking aid.**

**Standard Hospital procedures are to be taken in the event of an adverse effect and must be reported immediately (i.e. ‘Code Red’ and ‘Code Blue’).**

**Once the patient has consented to the trial, the patient will be encouraged to use the magnetic walking aid during the course of the trial unless there is an adverse effect, or they wish to withdraw from the trial.**

**The patient will be provided with a chart to record how many times they drop their walking aid daily, and complete a survey at the end of the 8-day intervention, or on the day they cease to require a walking aid, or on the day of discharge (whichever occurs first).**

**If a participant using the MWA still requires the aid post discharge, they are to be exchanged with a non-magnetic aid or an aid purchased separately.**

**The magnetic walking aids should not affect the course of treatment during the participant’s hospital stay, including medication use and other hospital-based interventions.**

# Study Procedures

## Study Evaluation Schedule

|  |  |  |
| --- | --- | --- |
| ASSESSMENT | SCREENING APPT. | DISCHARGE |
| Informed Consent to Pilot Study | **X** |  |
| Demographics/ Current Operation | **X** |  |
| Physiotherapy Initial assessment | **X** |  |
| MWA and SOC Information Form + Tutorial Given to Patient | **X** |  |
| Number of Times Walking Aid Dropped form | **X** |  |
| Follow Up questionnaire |  | **X** |
| Collect Number of Times Walking Dropped Form |  | **X** |

## Participating staff will be provided with a questionnaire at the conclusion of the study.

# Safety Assessment

**The overall risk of this invention study is low, however certain precautions should be taken for certain populations.**

**Potential risks identified:**

**Force of magnets: Patients unable to pull magnetic walking aids of walls and losing their balance, resulting in a fall.**

* **Solution: Establish in the initial tutorial whether the patient has the strength to use the magnetic walking aid. Standardized magnet strength, Walking stick Magnets: 1.5kg crutch magnets 2.5kg pull force.**

**Patient must disclose any implantable medical devices or metal implants.**

**Magnetic aids may interfere with cardiac pacemakers.**

* **Solution: Instruct the patients with pacemakers not to place the magnet within 30cm of their Pacemaker. Explain to them the risk that as long as the magnet is over their pacemaker it will set the pacemaker to a fixed rate of between 70-100bpm depending on the setting (manufactured setting). Once the magnet is removed it will return to normal function.**10–12

**Magnetic aids may interfere with implantable cardioverter-defibrillators (ICDs).**

* **Solution: Instruct the patients with ICD’s not to place the magnet within 30cm of their ICD. Explain to them the risk that as long as the magnets is over their ICD it will not deliver a vital shock. Once the magnet is removed it will return to normal function**10–12

**Magnetic aids may interfere with Insulin pump.**

* **Solution: Instruct the patients with insulin pumps not to place the magnet within 30cm of their pump. Ensure that they understand that magnetic fields may interfere with the pump’s motor. If the insulin pump shows a strange reading or the patient starts to feel signs and symptoms hypoglycemia the patient is instructed to communicate the problem to a nursing staff member.**

**Other metal implants: Aneurysm clips, Metallic fragments in the eye etc.**

* **Solution: List any metal implants on the patient informed consent form and ask the patient to sign acknowledging that they know the risks associated with using magnets.**

**Biological effects of neodymium magnets on the Cardiovascular System, Neural System and Skeletal system were inclusive.**13

# Intervention Discontinuation

**The intervention will be discontinued if the magnetic walking aid causes any bodily harm or the patient has any complications or concerns with using the magnetic walking aid. Also, participants can leave the study at any time without reason.**

# Statistical and Analytical Considerations

Primary:

**Assess the acceptability and accessibility of MWAs compared to standard walking aids in patients following joint replacement.**

**Outcome measures: descriptive statistics from the completed questionnaires and log book will be used to explore the acceptability and accessibility of the MWAs compared to the SWAs. All continuous analyses will be conducted using Welch’s t-tests . A Welch’s t-test is a robust version of the simple t-test that does not require equality of variance. Variables will be recoded based on a 1-5 scale (Likert scale) to compare acceptability and accessibility reported between the two groups.**

Secondary:

**Determine if the MWA reduces the number of occasions the walking aid comes to rest on the floor accidentally compared to the standard walking aid.**

**Outcome measures: a comparison between Control (SWA) and Intervention group (MWA) in the parallel trial, in terms of the number of times per day a walking stick comes to rest accidentally on the floor. This will be filled out each day on self-reported questionnaires completed by the study participants. The number of times the walking aid is dropped will be compared between groups using independent samples Mann-Whitney U test.**

**Regression analysis and descriptive statistics will be used to determine which patient characteristics are most significant in predicting the number of drops, as well as to predict how well the MWA is accepted. For logistic regression this will be expressed in terms of odds ratios.**

**Acceptability of the MWAs from the staff perspective will be explored using descriptive statistics from the completed staff questionnaire.**

**Any falls during the intervention period will be collected from the medical record to inform a power calculation for a future large-scale trial.**

# Participant Rights

**Participants will need to give written informed consent to participate in this study. Participants have the option to leave the study at any time without explanation. A patient’s decision to participate or not will not affect their care at Wolper Jewish Hospital. A staff member’s decision to participate or not will not affect their employment or their relationships within the hospital.**

# FUTURE DIRECTIONs of the study

**Run a similar study at Wolper Jewish Hospital in the Medical Ward on the ground floor where the medical conditions and reasons for admission are more varied. This will allow the hospital compare data between wards and improve in hospital care.**

# References

Reference

1. Sorock GS. Falls among the elderly: Epidemiology and prevention. *Am J Prev Med*. 1988;4(5):282-288. doi:10.1016/s0749-3797(18)31162-0

2. Gschwind Y, Wolf I, Bridenbaugh S, Kressig R. Basis for a Swiss perspective on fall prevention in vulnerable older people. *Swiss Med Wkly*. Published online November 21, 2011. doi:10.4414/smw.2011.13305

3. Härdi I, Bridenbaugh SA, Gschwind YJ, Kressig RW. The effect of three different types of walking aids on spatio-temporal gait parameters in community-dwelling older adults. *Aging Clin Exp Res*. 2014;26(2):221-228. doi:10.1007/s40520-014-0204-4

4. Lin M-R, Hwang H-F, Lin P-S, Chen C-Y. Relations of osteoporosis and follow-up duration to recurrent falls in older men and women. *Osteoporos Int*. 2014;25(3):863-871. doi:10.1007/s00198-013-2549-5

5. Morello RT, Barker AL, Watts JJ, et al. The extra resource burden of in‐hospital falls: a cost of falls study. *Med J Aust*. 2015;203(9):367-367. doi:10.5694/mja15.00296

6. Hitcho EB, Krauss MJ, Birge S, et al. Characteristics and circumstances of falls in a hospital setting. *J Gen Intern Med*. 2004;19(7):732-739. doi:10.1111/j.1525-1497.2004.30387.x

7. Luz C, Bush T, Shen X. Do Canes or Walkers Make Any Difference? NonUse and Fall Injuries. *Gerontologist*. Published online July 25, 2015:gnv096. doi:10.1093/geront/gnv096

8. Banierink H, ten Duis K, de Vries R, et al. Pelvic ring injury in the elderly: Fragile patients with substantial mortality rates and long-term physical impairment. Blank RD, ed. *PLoS One*. 2019;14(5):e0216809. doi:10.1371/journal.pone.0216809

9. Walking Cane Holder Frog. https://emobilityshop.com.au/products/walking-cane-holder-frog?variant=31955696975947&currency=AUD&utm\_medium=product\_sync&utm\_source=google&utm\_content=sag\_organic&utm\_campaign=sag\_organic

10. Wolber T, Ryf S, Binggeli C, et al. Potential interference of small neodymium magnets with cardiac pacemakers and implantable cardioverter-defibrillators. *Hear Rhythm*. 2007;4(1):1-4. doi:10.1016/j.hrthm.2006.09.012

11. Ryf S, Wolber T, Duru F, Luechinger R. Interference of neodymium magnets with cardiac pacemakers and implantable cardioverter-defibrillators: an in vitro study. *Technol Health Care*. 2008;16(1):13-18. http://www.ncbi.nlm.nih.gov/pubmed/18334784

12. How to use a magnet for pacemakers and ICDs - Core EM. https://coreem.net/procedures/how-to-use-a-magnet/

13. Yüksel C. The Use of Neodymium Magnets in Healthcare and Their Effects on Health. *North Clin Istanbul*. Published online 2017. doi:10.14744/nci.2017.00483

# Supplements / Appendices

Attached Follow up questionnaire

Attached Staff Survey

Attached ‘Number of Times Walking Aid Dropped floor