

A falls, balance and bone health clinic: analysis of patient characteristics and outcomes

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Synopsis

Protocol title: A falls, balance and bone health clinic: analysis of patient characteristics and outcomes

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Summary

Study title:	A falls, balance and bone health clinic: analysis of patient characteristics and outcomes
Protocol version	V1
Objectives	<p><i>Primary objective:</i></p> <ul style="list-style-type: none">- Provide a descriptive analysis of older adults that attend the Prince of Wales hospital falls, balance and bone health clinic.- Compare patients' attitude and intention towards clinic recommendations to patient participation in falls prevention recommendations at follow-up (six to nine months). <p><i>Secondary objectives:</i></p> <ul style="list-style-type: none">- Examine the association between patient demographic and health characteristics and outcomes collected at the Prince of Wales hospital falls, balance and bone health clinic (e.g. balance outcome measures, number of falls, clinic recommendations).- Evaluate the impact of clinic recommendations on falls related outcomes (number of falls, fear of falling)- Consider potential barriers to the uptake of clinic recommendations for community-dwelling older adults who have previously fallen or are at risk of falls.
Study design	Observational study.
Planned sample size	Routinely collected clinic data analysis: 252 Follow-up questionnaire: 80
Selection criteria	<p>Inclusion:</p> <p><u><i>Part 1 - Routinely collected clinic data analysis:</i></u></p> <ul style="list-style-type: none">- Retrospective data will be retrieved from the clinic records and electronic Medical Records (eMR) of all patients that attend the Prince of Wales hospital falls, balance and bone health clinic at least once between 1st February 2019 and either the 1st of August or the date ethics approval is obtained (whichever is the latter).- Prospective data will then be collected from attendees of the Prince of Wales hospital falls, balance and bone health clinic from the date of ethics approval until the end of the data extraction period (31st July 2021). <p><u><i>Part 2 - Follow-up questionnaire:</i></u></p> <ul style="list-style-type: none">- Patients that attend the Prince of Wales hospital falls, balance and bone health clinic at least once between 1st August 2019 and 31st January 2021 (dependent on ethical approval).

- Patients that receive some form of recommendation whilst attending the Prince of Wales hospital falls, balance and bone health clinic.
- Patients that are able and willing to provide written consent.

Exclusion:

Part 1 - Routinely collected clinic data analysis:

- Nil

Part 2 - Follow-up questionnaire:

- Patients that only attend the Prince of Wales hospital falls, balance and bone health clinic prior to 1st August 2019 (dependent on ethical approval).
- Patients assessed as having a severe cognitive impairment as per the Montreal Cognitive Assessment (MoCA) tool (cut off score: less than 10) during their falls, balance and bone health clinic appointment.
- Patients that do not have sufficient navigation of the English language to be able to complete the questionnaire.

Study procedure

Part 1 - Routinely collected clinic data analysis:

Extraction and analysis of retrospective and prospective re-identifiable data from the clinic files and electronic Medical Records (eMR) of patients that attend the Prince of Wales hospital falls, balance and bone health clinic. This will include key variables and outcomes documented in clinic files for the falls, balance and bone health clinic, as well as demographic information, hospitalisation information, and falls, balance and bone health clinic letters stored within the Prince of Wales hospital eMR database.

Part 2 - Follow-up questionnaire:

A smaller sample of patients that attend the Prince of Wales hospital falls, balance and bone health clinic will be invited to participate in a follow-up questionnaire six to nine months after they attend the clinic. The aim of this questionnaire is to compare patient attitudes and intentions to patient actions in relation to falls prevention recommendations.

Data will be re-identifiable by members of the research team that hold an appointment with, or are on student placement (under the supervision of the research team) at the Prince of Wales hospital only by a code key stored on the Prince of Wales hospital network. This is required to allow for linkage of data for patients seen multiple times at the falls, balance and bone health clinic during the study period, and/or who provide written consent to participate in a follow-up questionnaire six to nine months after their clinic appointment.

Data will be shared across the Prince of Wales hospital and Macquarie University secure networks between the research

team. This data will have all identifiable information other than the unique study identification code removed.

All study results presented in publications will be non-identifiable and presented as group results.

Statistical considerations

Sample size calculation:

Part 1 - Routinely collected clinic data analysis:

Data will be extracted for approximately 252 patients. This sample size is based on previous annual falls, balance and bone health clinic attendances (average nine per month).

Part 2 - Follow-up questionnaire:

Approximately 80 patients will participate in the follow-up questionnaire. This sample size is based on previous annual falls, balance and bone health clinic attendances (average nine per month) minus the potential loss of participants due to decline or inability to consent, no follow-up intervention required, and death of the patient.

Analysis plan:

Descriptive analyses and regression modelling will be used to quantitatively examine the associations between study variables, such as patient demographics, physical ability, medications, bone health, service use and falls risk.

Duration of the Study

30 months

TABLE OF CONTENTS

1.	BACKGROUND	9
1.1.	DISEASE BACKGROUND*	9
1.2.	RATIONALE FOR PERFORMING THE STUDY*	9
2.	STUDY OBJECTIVES*	10
2.1.	PRIMARY OBJECTIVE*	10
2.2.	SECONDARY OBJECTIVES	10
3.	STUDY DESIGN*	11
3.1.	DESIGN*	11
3.2.	STUDY GROUPS	11
3.3.	NUMBER OF PARTICIPANTS*	11
3.4.	NUMBER OF CENTRES	12
3.5.	DURATION	12
4.	PARTICIPANT SECTION	12
4.1.	INCLUSION CRITERIA*	12
4.2.	EXCLUSION CRITERIA*	13
5.	STUDY OUTLINE*	13
5.1.	STUDY FLOW CHART	13
5.2.	INVESTIGATION PLAN*	14
5.3.	STUDY VARIABLES	14
5.4.	STUDY PROCEDURE BENEFITS	16
5.5.	STUDY PROCEDURE RISKS*	16
5.6.	RECRUITMENT AND SCREENING*	17
5.7.	INFORMED CONSENT PROCESS*	18
5.8.	ENROLMENT PROCEDURE*	18
6.	SAFETY*	18
6.1.	ADVERSE EVENT REPORTING*	18
6.2.	EARLY TERMINATION	19
7.	STATISTICAL CONSIDERATIONS*	19
7.1.	SAMPLE SIZE OR POWER CALCULATION*	19
7.2.	STATISTICAL ANALYSIS PLAN*	19
8.	STORAGE AND ARCHIVING OF STUDY DOCUMENTS*	20
9.	REFERENCES*	21
10.	APPENDICES	22
10.1.	FOLLOW-UP QUESTIONNAIRE (INCLUDES THE FALLS EFFICACY SCALE INTERNATIONAL)	22

10.2.	PATIENT INFORMATION AND CONSENT FORM	26
10.3.	DATA COLLECTION SHEET	30
10.4.	DATA EXTRACTION FORM	32

1. BACKGROUND

1.1. DISEASE BACKGROUND*

The trends of the ageing population observed in Australia reflects the changes happening on a global level. In 2010, 14% of the Australian population (3 million people) were 65 years or older, and this is expected to rise to 23% (8.1 million people) by 2050.¹ Ageing is associated with a decline in physical, sensory and cognitive health, which can result in an increased risk of falls. A fall is defined as ‘an event which results in a person coming to rest inadvertently on the ground or floor or other lower level’.² Worldwide it is estimated that 28-35% of people aged 65 years and older have at least one fall every year, which increases to 32-43% of people over the age of 70.³ Falls have a significant physical, psychological and financial impact on the older person (aged 65 years or older), their family, carers and the wider community. During the 2006/07 financial year the total cost of healthcare related to fall injuries of older people in New South Wales (NSW), Australia was estimate to be AU\$558.5 million.⁴

Risk factors for falls can be categorised into four main interacting groups: biological, behavioural, environmental, and socioeconomic.³ Biological risk factors are characteristics that pertain to the body, such as age, gender and comorbidities.³ Behavioural risk factors are those associated with human actions, emotions and daily choices, including poor self-perceived health status and fear of falling.³ Environmental risk factors are those that involve interplay of person’s physical conditions and the surrounding environment, such as hazards within the home and community.³ Socioeconomic risk factors are those that influence social conditions and economic status, such as certain occupations and poverty.³ When trying to reduce falls among older people it is important to consider the different risk factors and which ones are potentially modifiable, these may be through changes made by the individual or utilization of supportive services.

In Australia, majority of older Australians (94%) live in their own homes within the community.⁵ It is estimated that one in three community-dwelling older adults will have at least one fall per year.⁶ Despite the high incidence of falls among this population, there are often difficulties associated with collecting accurate data about falls occurring in the community. Falls clinics are one potential source of data. They generally provide a multidisciplinary assessment for individuals at risk of falls, and accordingly make recommendations or implement targeted falls and falls injury-prevention strategies.⁷ One example is the falls, balance and bone health clinic at the Prince of Wales hospital which reviews older adults (aged 65 years and older) that have had a previous fall or are at high risk of falling. The routine data collected in this clinic is a valuable source of information about adults that have fallen or at risk of falling.

1.2. RATIONALE FOR PERFORMING THE STUDY*

This study will help to develop the current research base on falls among community-dwelling older adults. Previous studies have considered the characteristics of falls clinic patients however majority had relatively small sample sizes (36-150 participants),⁸⁻¹⁰ and/or were conducted over short study periods (6-12 months).⁷⁻¹⁰ This study will use longitudinal data that will help to maximise the study sample, and allows for evaluation of falls, balance and bone health clinic recommendations for patients that consent to participate in a follow-up questionnaire (see Appendix 10.1:

follow-up questionnaire and Appendix 10.2: participant information and consent form) and/or attend review appointments during the study period.

The findings of this study will provide a descriptive analysis of the patients that attend the Prince of Wales hospital falls, balance and bone health clinic. It will also provide insight into associations between the different factors collected during clinic appointments (e.g. patient characteristics, balance, fear of falling, bone health, patient's attitude and intention to falls, balance and bone health clinic recommendations). This study will compare patients' attitude and intention to action taken in relation to recommendations provided to older adults seen in the Prince of Wales hospital falls, balance and bone health clinic, and highlight patient perceived barriers to falls prevention recommendations. Such information can inform current practice within the Prince of Wales hospital falls, balance and bone health clinic, and guide future research to help improve falls prevention services for older adults in the community.

Hypotheses

Patients that attend the Prince of Wales hospital falls, balance and bone health clinic will have multiple falls risk factors.

Patients that have a positive attitude and intention towards falls prevention recommended by health professionals (doctors and physiotherapists) will be more likely to participate in such recommendations.

Patients that participate in multi-component recommendations (e.g. Stepping On falls prevention program) will have greater improvements in outcomes (e.g. number of falls, fear of falling) compared to patients in single component recommendations (e.g. medication review).

Patients who are assessed as having a high probability of further falls ($\geq 27\%$ in the QuickScreen¹¹) will have greater improvements in outcomes compared to patients who are assessed as having a low probability of further falls ($\leq 13\%$ in the QuickScreen¹¹).

2. STUDY OBJECTIVES*

2.1. PRIMARY OBJECTIVE*

- Provide a descriptive analysis of older adults that attend the Prince of Wales hospital falls, balance and bone health clinic.
- Compare patients' attitude and intention towards falls, balance and bone health clinic recommendations to patient action at follow-up (six to nine months after clinic appointment).

2.2. SECONDARY OBJECTIVES

- Evaluate the association between the different factors and outcomes collected at the Prince of Wales hospital falls, balance and bone health clinic (e.g. patient characteristics, medications, balance outcome measures, falls, balance and bone health clinic recommendations).
- Evaluate the impact of falls, balance and bone health clinic recommendations on falls related outcomes (number of falls, fear of falling)

- Consider potential barriers to the uptake of falls prevention recommendations for community-dwelling older adults who have previously fallen or are at risk of falls.

3. STUDY DESIGN*

3.1. DESIGN*

A two-part longitudinal, observational study will be used to address the objectives outlined above. Part 1 of the study will use a combination of retrospective and prospective, re-identifiable data routinely collected from the Prince of Wales hospital falls, balance and bone health clinic files and electronic Medical Records (eMR) database between the 1st of February, 2019 and 31st of July, 2021.

Part 2 of the study will involve a follow-up questionnaire completed via telephone by patients that consent to be involved in this element of the study six to nine months after their clinic appointment (see Appendix 10.1: follow-up questionnaire and Appendix 10.2: participant information and consent form).

3.2. STUDY GROUPS

Older adults (aged 65 years and older) are referred to the falls, balance and bone health clinic either by their GP, Emergency Department, specialist or the fracture clinic when they have had a fall, are identified as a high risk of falls or sustained a fracture. All patients that are referred to and attend the Prince of Wales falls, balance and bone health clinic at least once between 01/02/2019 - 31/07/2021 will be involved in part 1 of the study, collecting data from their clinic files and the eMR.

A sub-group of patients attending the clinic between 01/08/2019 – 31/01/2021 (dependent on ethics) will be invited to partake in part 2 of the study. This sub-group must provide consent, not have a severe cognitive impairment and have sufficient navigation of the English language to complete the follow-up questionnaire.

3.3. NUMBER OF PARTICIPANTS*

In previous years an average of nine patients per month were seen in the Prince of Wales falls, balance and bone health clinic. It is expected that similar numbers (if not more) will be reviewed over the coming years. Based on these figures it is expected that part 1 of the study will analyse re-identifiable data for 252 patients who attend the Prince of Wales hospital falls, balance and bone health clinic between 01/02/2019-31/07/2019.

The sample size for part 2 of the study (follow-up questionnaire) will be smaller due to the inability to collect consent from patients that attend the Prince of Wales falls, balance and bone health clinic prior to 01/08/2019 (pending ethical approval), patients decline to complete the follow-up questionnaire, patients may not require any follow-up intervention post clinic appointment, difficulty contacting patients six to nine months following their clinic appointment and the possibility that patients die during the study period. Therefore, the potential sample size for the follow-up questionnaire is estimated to be approximately 80. This figure is approximately half of the expected patient attendance rate for the data collection period (based on previous attendance rates for the Prince of Wales hospital falls, balance and bone health clinic).

3.4. NUMBER OF CENTRES

This is a single centre study located in the eastern suburbs of Sydney, NSW: The Prince of Wales hospital falls, balance and bone health clinic. This clinic is attended by a team of geriatricians, physiotherapists and a nurse. All patients complete a geriatrician consultation, and mobility and falls related outcome measures with the physiotherapist.

3.5. DURATION

The 30-month study will run between 01/08/2019 and 31/01/2022 (dependent on ethical approval). During this time re-identifiable data will be extracted on a regular basis during the data extraction period (01/11/2020 - 31/07/2021).

The following key milestones will be delivered (also see Table 1 in section 5.2, investigation plan):

- SESLHD research ethics – submission and attainment of research ethics clearance (month 1).
- Develop and finalise data collection forms (months 1 and 2).
 - Key code to be used to de-identify data for analysis and to re-identify data as required for data linkage (only accessed by research team members that hold an appointment with or are on student placement under the supervision of the research team at the Prince of Wales hospital that usually have access to this information).
 - Data extraction form to record patient's unique study identification code (re-identifiable by limited research team members as stated above) and non-identifiable data from clinic files and eMR for all patients that attend the Prince of Wales hospital falls, balance and bone health clinic.
 - Follow-up questionnaire (other than the unique study identification code all information collected will be non-identifiable)
- Commence recruitment for follow-up questionnaires (month 3)
- Commence data extraction on a regular basis (month 4)
- Commence follow-up questionnaires (month 9)
- Complete recruitment for follow-up questionnaires (month 18)
- Complete data extraction (month 24)
- Complete follow-up questionnaires (month 24)
- Commence data analysis (month 25)
- Complete data analysis (month 28)
- Compile manuscript of research findings and disseminate through appropriate means, e.g. peer-reviewed journal, submission of abstract to relevant conference, Prince of Wales Geriatric Clinical Teaching sessions and staff meetings (months 28-30)

4. PARTICIPANT SECTION

4.1. INCLUSION CRITERIA*

Part 1 - Routinely collected clinic data analysis:

All patients that attend the Prince of Wales hospital falls, balance and bone health clinic at least once between 1st February 2019 and 31st July 2021.

Part 2 - Follow-up questionnaire:

Patients that attend the Prince of Wales hospital falls, balance and bone health clinic at least once between 1st August 2019 and 31st January 2021 (dependent on ethical approval).

Patients that receive some form of recommendation whilst attending the Prince of Wales hospital falls, balance and bone health clinic.

Patients that provide written consent to complete a questionnaire approximately six to nine months after their clinic appointment.

4.2. EXCLUSION CRITERIA*

Part 1 - Routinely collected clinic data analysis:

Nil

Part 2 - Follow-up questionnaire:

Patients that only attend the Prince of Wales hospital falls, balance and bone health prior to 1st August 2019 (dependent on ethical approval).

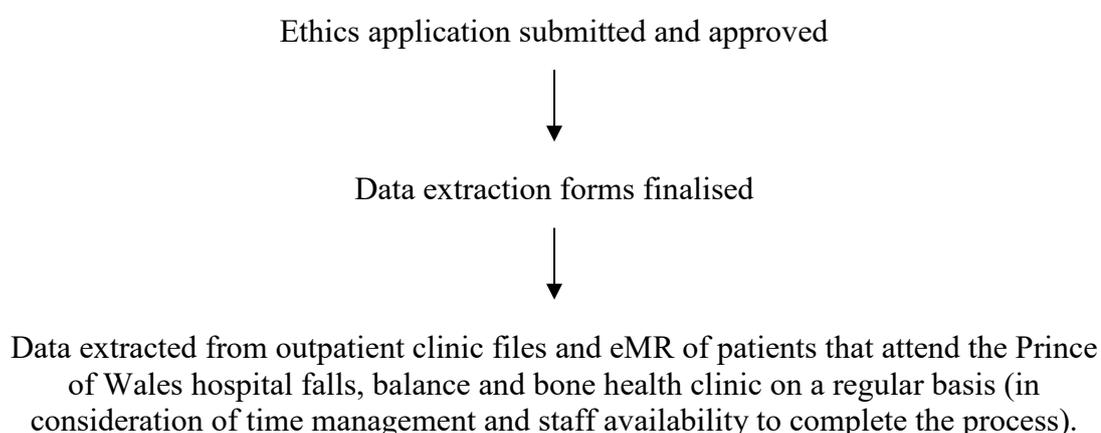
Patients that do not require any follow-up intervention after attending the Prince of Wales hospital falls, balance and bone health clinic.

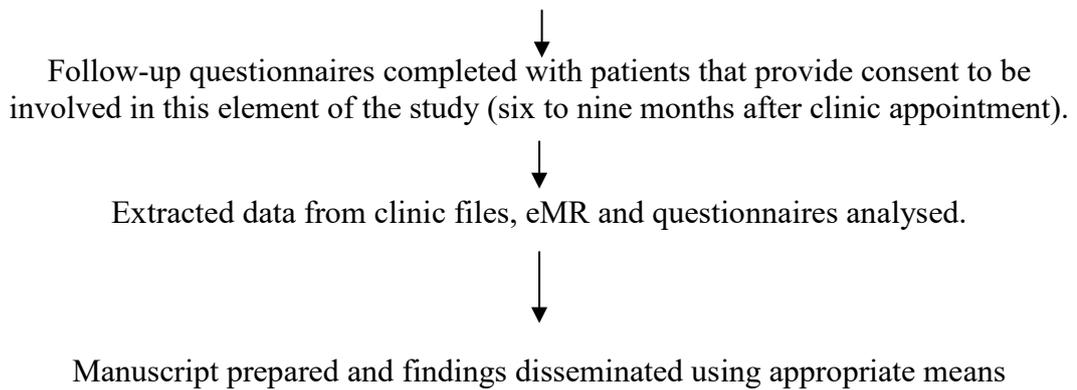
Patients assessed as having a severe cognitive impairment as per Montreal Cognitive Assessment (MoCA) tool (cut off score: less than 10)¹² during their falls, balance and bone health clinic appointment.

Patients that do not have sufficient navigation of the English language to be able to answer the questionnaire.

5. STUDY OUTLINE*

5.1. STUDY FLOW CHART





5.2. INVESTIGATION PLAN*

Table 1. Projected study plan and milestones.

Activity	Month														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Ethics application and approval															
Finalise data collection documents															
Recruitment for follow-up questionnaires															
Data extraction															
Conduct follow-up questionnaires															
Activity	Month														
	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Recruitment for follow-up questionnaires															
Data extraction															
Conduct follow-up questionnaires															
Data analysis															
Manuscript and dissemination															

5.3. STUDY VARIABLES

Part 1 - Routinely collected clinic data analysis:

Retrospective and prospective data extracted and analysed for this element of the study will include variables routinely collected in the Prince of Wales hospital falls, balance and bone health clinic files and the hospital's eMR database, as follows (see Appendix 10.3: data collection sheet, and Appendix 10.4: data extraction form):

- Falls, balance and bone health clinic date of attendance
- Age
- Gender
- Height
- Weight
- Country of birth
- Language
- Marital status
- Home postcode
- Comorbidities
- Clinical investigation results (e.g. CT scans, blood tests)
- Medications
- MoCA¹² or Rowland Universal Dementia Assessment Scale (RUDAS)¹³ score

- Use of glasses (including type)
- Mobility (including walking aid)
- Functional ability (ability to complete activities of daily living)
- Social history
 - Type of home
 - Who they live with
 - Support services used (formal and/or informal)
- Bone health history
 - Fracture history
 - Smoking/ETOH history
 - DEXA results
 - Vitamin D levels
 - Calcium levels
 - Dietary Intake
 - pQCT results
- QuickScreen¹¹ score
 - Total number of falls risk factors
 - Probability of falls in the following 12 months (%)
 - Number of medications
 - Psychotropic medications
 - Five times sit to stand time
 - Falls History (previous 12 months)
 - Low contrast vision acuity result
 - Tactile sensitivity test result
 - Semi-tandem stand time
 - Alternate step time
- Timed Up and Go (TUG) test¹⁴ time
- 10m walk test¹⁵ time
- Falls Efficacy Scale – International (FES-I)¹⁶
- Attitudes to Falls-Related Interventions Scale (AFRIS)¹⁷
- Recommendation from the falls, balance and bone health clinic appointment (e.g. referral to Stepping On falls prevention program, specialist review)
- Hospitalisation data
 - Admission date
 - Reason for admission
 - Length of stay

Part 2 - Follow-up questionnaire:

Data collected and analysed for this element of the study will include the following variables (see Appendix 10.1: follow-up questionnaire):

- Patient's action based on recommendation(s) from the Prince of Wales hospital falls, balance and bone health clinic and self-sought alternative.
- If recommendations not followed, the reasons for not following recommendation(s) from the Prince of Wales hospital falls, balance and bone health clinic.
- Attendance at alternative falls prevention programs
- Patient opinion on Prince of Wales hospital falls, balance and bone health clinic recommendation and/or alternative program
- Falls history (since clinic appointment)
- FES-I¹⁶

5.4. STUDY PROCEDURE BENEFITS

This study does not have any potential individual benefits for participants. However, it can inform current practice within the Prince of Wales hospital falls, balance and bone health clinic, and guide future research to help improve falls prevention services for older adults in the community.

5.5. STUDY PROCEDURE RISKS*

Table 2. Identified potential risks and corresponding mitigation strategies to minimize risk.

The Risk <i>What can happen?</i>	Source <i>How can this happen?</i>	Impact <i>From event happening</i>	Risk mitigation <i>treatment</i>	Likelihood¹	Consequence²	Risk rating³
Ethics approval for study delayed.	Ethics committee questions aspects of the study proposal.	The study start date may be delayed.	Careful consideration of all ethics committee requirements. The research team have previous experience and knowledge in ethics procedures in this field of research.	Possible	Minor	Low
Difficulty in extracting data from either the clinic files or the eMR database.	The quality of data required for the study is sub-optimal or not easily accessible.	This could require extra time to ensure quality of data extraction.	Data fields will be determined prior to extraction and standardised form developed. The research team have previous experience in extracting and cleaning similar datasets in healthcare settings.	Unlikely	Moderate	Low
Staff resource problems.	Inability to obtain adequate staff resources to undertake research.	Delays in undertaking the research.	The research team comprises of a mixture of experienced researchers and clinicians from the Prince of Wales hospital and Macquarie University. The research team has the flexibility to readjust or reallocate resources from different areas as necessary. Macquarie University doctorate of physiotherapy students will assist intermittently with data extraction and analysis.	Unlikely	Moderate	Low
During completion of follow-up questionnaire, patients may identify that	Patient decided not to followed recommendations from the falls, balance and bone health clinic.	Patients may fall and/or sustain falls-related injuries in the future.	Where appropriate, patients will be advised (during follow-up questionnaires) to see their General Practitioner for a medical review and	Possible	Insignificant – severe (case-by-case dependent)	Low – high (case-by-case dependent)

The Risk What can happen?	Source How can this happen?	Impact From event happening	Risk mitigation treatment	Likelihood¹	Consequence²	Risk rating³
they have not completed the clinic recommendation and therefore are potentially at a high risk of falls.*			consideration of alternative falls prevention interventions.			
Insufficient sample recruited for the follow-up questionnaires.	Some patients may decline to complete the follow-up survey.	Less data to analyse, limiting the conclusions that can be drawn from this element of the study.	All potential participants that meet the inclusion criteria will be invited to participate in this element of the study. The research team will work with the available data based on consent provided.	Possible	Moderate	Low

¹Likelihood: Rare, Unlikely, Possible, Likely, Almost Certain

²Consequence: Insignificant, Minor, Moderate, Major, Severe

³Risk Rating: Low, Medium, High, Extreme

*Such individuals would not routinely be followed up and identified and remain at risk of falls, therefore this process will most likely only have a positive outcome, compared to no follow-up at all.

5.6. RECRUITMENT AND SCREENING*

Part 1 - Routinely collected clinic data analysis:

Data will be collected for all patients that attend the Prince of Wales falls, balance and bone health clinic between 01/02/2019-31/07/2021. Patients will be identified by review of the falls, balance and bone health clinic attendance list by members of the research team that hold an appointment with or are on student placement (under the supervision of the research team) at the Prince of Wales hospital and usually have access to the data.

Part 2 - Follow-up questionnaire:

All patients that attend the Prince of Wales hospital falls, balance and bone health clinic between 01/08/2019-31/01/2021 (dependent on ethical approval), receive some form of recommendation whilst attending their clinic appointment, do not have a severe cognitive impairment (as determined by a score of less than 10 on the MoCA tool during their appointment), and have sufficient navigation of the English language to answer questions will be invited to participate in a follow-up questionnaire six to nine months after their clinic appointment. A member of the research team who holds an appointment with, or is on student placement (under the supervision of the research team) at the Prince of Wales hospital will conduct the follow-up questionnaires. They will contact the patients that provide written consent at their clinic appointment six to nine months after attendance via telephone call. Prior to making the call, the research team member will check the Prince of Wales eMR to ensure the patient is not deceased. The research team member will make three attempts to contact the patient, if unsuccessful the patient will be deemed loss to follow-up.

5.7. INFORMED CONSENT PROCESS*

Part 1 - Routinely collected clinic data analysis:

Consent will not be gained directly from patients for data extracted from the Prince of Wales hospital clinic files and eMR. This process will be completed by members of the research team that hold an appointment with or are on student placement (under the supervision of the research team) at the Prince of Wales hospital and normally have access to the routinely collected data.

Part 2 - Follow-up questionnaire:

Informed written consent will be collected for participation in the follow-up questionnaire during patient's attendance at the Prince of Wales falls, balance and bone health clinic (see Appendix 10.2: participant information and consent form). All patients that provide written consent during their appointment will then be contacted via telephone call approximately six to nine months later, at this time consent will be reconfirmed prior to commencing the questionnaire.

5.8. ENROLMENT PROCEDURE*

Part 1 - Routinely collected clinic data analysis:

This element of the study will not require patients to enroll and there will be no option to review the data by patients as it only involves the (retrospective and prospective) collection of routine data from the Prince of Wales falls, balance and bone health clinic. Attendance lists from the falls, balance and bone health clinic will be reviewed on a regular basis to ascertain which patient clinic files and eMR need to be accessed to collect the required data.

Part 2 - Follow-up questionnaire:

Patients that attend the Prince of Wales falls, balance and bone health clinic between 01/08/19-31/01/2021 (dependent on ethical approval), receive some form of recommendation whilst attending their clinic appointment, do not have a severe cognitive impairment (as determined by a score of less than 10 on the MoCA tool during their appointment), and have sufficient navigation of the English language to answer questions will be provided information on this element of the study and the opportunity to participate in the follow-up questionnaire. Patients can then decide if they would like to provide informed consent, and will be advised that their decision will not impact the care they receive at the Prince of Wales falls, balance and bone health clinic or any interactions they have with the research team or any Prince of Wales hospital staff. When patients are contacted six to nine months after their clinic appointment they will have the opportunity to review their consent and their responses prior to data analysis.

6. SAFETY*

6.1. ADVERSE EVENT REPORTING*

Part 1 - Routinely collected clinic data analysis:

Adverse event reporting is not required for this study as it is an observational study that does not include a study intervention and therefore will not result in any

discomfort or risk for patients that attend the Prince of Wales hospital falls, balance and bone health clinic.

Part 2 - Follow-up questionnaire:

If patients identify that they have not followed the recommendation(s) from the Prince of Wales falls, balance and bone health clinic (question 1a), or have had further falls since their clinic appointment (question 3) they will potentially still be at a high risk of falls. Therefore, at the end of the questionnaire they will be prompted by the research member conducting the telephone call to see their General Practitioner for a medical and/or falls review (see Appendix 10.1: follow-up questionnaire).

6.2. EARLY TERMINATION

The only potential reason for early termination is if the Prince of Wales hospital falls, balance and bone health clinic was ceased, which is extremely unlikely. However, if this did occur data extraction would cease and analysis would be completed only on data extracted up until that time point. This would be reported by the chief investigator to the ethics committee and in the final study report.

7. STATISTICAL CONSIDERATIONS*

7.1. SAMPLE SIZE OR POWER CALCULATION*

This is a population-based study of all patients that attend the falls, balance and bone health clinic at the Prince of Wales hospital, NSW. Therefore, the proposed number of patients that will be analysed in this study is based on the Prince of Wales hospital falls, balance and bone health clinic attendance rates in previous years; an average of nine patients are seen monthly. In this study, data will be extracted from a 30 months period (01/02/2019-31/07/2021), it is expected that similar attendance rates will be achieved and result in a proposed sample size of 252 patients. Consent to participate in the follow-up questionnaires will not be collected until after ethical approval is granted (01/08/2019-31/01/2021 - dependent on ethical approval), the potential sample size for this element of the study is 80 patients.

7.2. STATISTICAL ANALYSIS PLAN*

In order to address the study objectives, descriptive analyses and regression modelling of routinely collected data from the Prince of Wales hospital falls, balance and bone health clinic and follow-up questionnaires will be used to quantitatively examine the associations between study variables, such as patient demographics, physical ability, medications, service use, number of falls, fear of falling, patient's attitudes and intentions to clinic recommendations, and patient's actions based on clinic recommendations.

The demographic, health characteristics and falls risk factors of patients attending the clinic will be tabulated. Chi-square tests (for categorical variables) and t-tests (for continuous variables) will be used to compare clinic outcomes (e.g. balance outcome measures) among different patient groups. Outcomes at follow up (e.g. number of falls) will be compared between patients attending different falls prevention activities using negative binomial regression models.

Regression modelling will be used to determine whether patients' attitudes and intentions (as measured by the AFRIS¹⁷) are associated with their participation in falls prevention recommendations, while accounting for other factors that may be associated with participation (e.g. health factors).

Potential barriers to the uptake of clinic recommendations will be examined using thematic analysis of clients' responses to question 1b in the follow-up questionnaire (see Appendix 10.1).

8. STORAGE AND ARCHIVING OF STUDY DOCUMENTS*

Data will be extracted from the Prince of Wales hospital clinic files and eMR by members of the research team that hold an appointment with or are on student placement (under the supervision of the research team) at the Prince of Wales hospital and usually have access to this information. Approval from the Medical Records department to access clinic files for this study will be sought prior to commencement of study when completing the required governance paperwork. Clinic files will be requested from the Medical Records department using the *Application for Access to Medical Records for Review* form at each data extraction period and viewed on site at the Prince of Wales hospital.

To maintain confidentiality each patient will be allocated a unique study identification code and all identifiable data removed (i.e. MRN number, only postcode will be retained for address, only year of birth retained for date of birth). A code key will be created and stored within the Prince of Wales secure network that links patients' MRNs to their unique study identification code. This will allow for reidentification and linkage of data for patients that complete the follow-up questionnaire and/or attend the falls, balance and bone health clinic more than once during the study period. This process will be completed by members of the research team that hold an appointment with or are on student placement (under the supervision of the research team) at the Prince of Wales hospital and usually have access to this information. Only re-identifiable data will be shared and utilized for analysis amongst the research team via Prince of Wales hospital and Macquarie University secure networks that are password protected for data analysis.

All data and reports will be stored electronically on password-protected servers at the Prince of Wales hospital and Macquarie University. Only investigators approved by the Research Ethics Committee will have access to the data. Records will be retained for 5 years from the date of the most recent publication in accordance with the Records Act - General Retention and Disposal Authority University Records (GDA 23) (2005) and the Australian Code for the Responsible Conduct of Research (2007). Any data presented in publications, conferences or reports will be non-identifiable.

9. REFERENCES*

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10. APPENDICES

10.1. FOLLOW-UP QUESTIONNAIRE (INCLUDES THE FALLS EFFICACY SCALE INTERNATIONAL)



Health
South Eastern Sydney
Local Health District

Falls, balance and bone health clinic follow-up questionnaire

Hi _____,

My name is _____ and I am a researcher working on a study being conducted by Prince of Wales Hospital and Macquarie University. I am calling as you had previously attended the Prince of Wales - falls, balance and bone health clinic. During your visit which took place approximately 6-9 months ago, you had consented to receiving a follow-up call from us regarding your history of falls, whether you undertook the clinics recommendations, as well as your current concerns around falling.

This questionnaire will take approximately 10-15 minutes, are you still happy to answer these questions?

Yes (please proceed with below questions) No (thank them for their time and hang up)

Questions

Q1. At your last review on the ___/___/20___, the team from the falls, balance and bone health clinic recommended you to the following services/referrals:
[Researcher to **number** as many as are relevant **from clinic files prior to phone call**]

Falls prevention program e.g. Stepping On, ~~REAP~~, AIM
 Specialist Review: _____
 Investigation: _____
 Change in medication: _____
 Other: _____

Q1.a) Have you followed up this referral method?

Service/ Referral #1: _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No (If No, go to Q1.b)
Service/ Referral #2: _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No (If No, go to Q1.b)
Service/ Referral #3: _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No (If No, go to Q1.b)
Service/ Referral #4: _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No (If No, go to Q1.b)
Service/ Referral #5: _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No (If No, go to Q1.b)

Q1.b) Can you please elaborate on the reason for **not following** the recommendations provided by the falls, balance and bone clinic?

Q3.c) Are there any factors that you contribute to the fall you have reported? If so, please elaborate.

Q4. Fall Efficacy Scale – International (FES-I)

Now we would like to ask some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently don't do the activity (e.g. if someone does your shopping for you), please answer to show whether you think you would be concerned about falling IF you did the activity. For each of the following activities, please indicate which is closest to your own opinion to show how concerned you are that you might fall if you did this activity.

Item	Question	Not at all Concerned 1	Somewhat Concerned 2	Fairly Concerned 3	Very Concerned 4
1	Cleaning the house (e.g. sweep, vacuum or dust)				
2	Getting dressed or undressed				
3	Preparing simple meals				
4	Taking a bath or shower				
5	Going to the shop				
6	Getting in or out of a chair				
7	Going up or down stairs				
8	Walking around in the neighbourhood				
9	Reaching for something above your head or on the ground				
10	Going to answer the telephone before it stops ringing				
11	Walking on a slippery surface (e.g. wet or icy)				
12	Visiting a friend or relative				
13	Walking in a place with crowds				
14	Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)				
15	Walking up or down a slope				
16	Going out to a social event (e.g. religious service, family gathering or club meeting)				

Note: If a participant answered 'No' to Q1.a) regarding follow-up of referral, or has reported a fall, please state the following prior to finalising the phone call.

“Based on your last assessment at the falls, balance and bone health clinic and/or your reported recent history of falls - we recommend that you visit your GP, just to ensure appropriate services are recommended to you that you may require.”

That concludes our question for today. Thank you very much for the time taken to answer these responses. If you have any concerns related to the project, please call Dr Lindsey on (02) 9850-2487.

Thank you once again.
[Hang up]

Collected by: _____

Signature: _____

Collection Date: ____/____/____

Patient Study ID: _____

10.2. PATIENT INFORMATION AND CONSENT FORM



MACQUARIE
University
SYDNEY AUSTRALIA



Health
South Eastern Sydney
Local Health District

Physiotherapy Department, Prince of Wales Hospital,
320-346 Barker Street, Randwick, NSW 2031
Phone: (02) 9850-2487
Fax: (02) 9850-6630
Email: lindsey.brett@mq.edu.au

Chief Investigator's Name & Title: Dr. Lindsey Brett – Post Doctoral Research Fellow

Participant Information and Consent Form

Project: A falls, balance and bone health clinic: analysis of patient characteristics and outcomes.

Research indicates that falls are a major health issue in Australia with over 30% of community dwelling adults over the age of 65 years experiencing at least one fall per year. These numbers are likely to rise given Australia's ageing population. Evidence suggests that the use of programs to prevent falls appears to address this issue.

The falls, balance and bone health clinic at Prince of Wales identified individuals at risk of falling and provides relevant referral to manage this. The aim of this study is to provide a description of the individuals that attend the falls clinic, monitor utilisation of referred programs and to track the impact of these program on reducing the number of reported falls.

This Participant Information and Consent Form tells you about the research project, and what your potential involvement will involve. Knowing what is involved will help you decide if you would like to participate. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

If you decide to participate, you will be asked to sign the consent section of this document. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

Who is carrying out the study?

This study is being conducted by Dr Lindsey Brett & Dr Katherine Scrivener from the Department of Health Professions at Macquarie University in collaboration with Dr Daniel Treacy from the Physiotherapy Department at Prince of Wales Hospital. Please note there will also be a research assistant and students from the Doctorate of Physiotherapy program at Macquarie University working on this project under the supervision of Dr Brett, Dr Scrivener and Dr Treacy.

Relevant information about the research project

You have been invited to participate in this study since you are attending the falls, balance and bone health clinic at Prince of Wales Hospital. We are looking for participants to complete a short (10-15 minute) questionnaire over the phone, approximately 6-9 months following today's review at the clinic.



To be eligible for this, we are who:

- Are attending the falls, balance and bone health clinic at Prince of Wales Hospital
- Receive some form of recommendation whilst attending the clinic.
- Are aged 65 years or older
- Have a sufficient level of the English language to complete a questionnaire over the phone
- Have no cognitive impairment affecting the ability to provide consent and complete a questionnaire.

Is participation in this study voluntary?

Participation in this study is entirely voluntary. You are not obligated to participate, and if you decide to participate, you are free to withdraw at any time without having to give a reason and without consequence. Your decision to not be involved in the project will not affect your relationship with Macquarie University or Prince of Wales Hospital. You are able to edit or remove your data from this study prior to the analysis period, please contact Dr Lindsey Brett to do so.

What does participation in this research involve?

If you agree to participate, you will be asked to complete a short survey (approximately 10 - 15 minutes) over the phone in approximately 6-9 months' time from your clinical review at the falls, balance and bone health clinic at Prince of Wales Hospital. In the survey, we will ask you [questions](#) and feedback related to any falls prevention programs you have been involved in, your history of falls and your self-perceived confidence in performing everyday tasks.

Are there any benefits and/or risks to participating in this survey?

There is no individual benefit associated with involvement in this study. However, your responses to this questionnaire will potentially help improve current practice within the falls, balance and bone health clinic.

Aside from the time-burden of completing the survey, there is no anticipated burden associated with involvement in this study. If at any time the questions that are asked are distressing, you are free to stop the questionnaire and withdraw from the study without consequence.

What will happen to information about me?

By signing the consent [form](#) you consent to the research team collecting and using personal information about you for the research project. We anticipate publishing the results of this study in journals and at conferences, however, in all circumstances, all information will be de-identified and published as group numbers only. Information will only be accessible to the researchers involved in this project. In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team.

Can I contact the researchers?

If you have any questions related to this study, please contact a member Dr Lindsey Brett either by email (lindsey.brett@mq.edu.au) or over the phone (9850-2487).

Who has reviewed the research project?

This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Support Office which is nominated to receive complaints from research participants. You should contact them on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote [\[HREC project number\]](#).



**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the consent section below.
This information sheet is for you to keep.**

Consent Form [Participant Copy]

1. I _____, agree to participate in the study described in the participant information statement set out above.
2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
4. I understand that I can withdraw from the study at any time without prejudice to my relationship to either Prince of Wales Hospital or Macquarie University.
5. I agree that research data gathered from the results of the study may be published, ~~provided that~~ I cannot be identified.
6. I understand that if I have any questions relating to my participation in this research, I may contact Dr Lindsey Brett, who will be happy to answer them.
7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Support Office, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, email SESLHD-RSO@health.nsw.gov.au ;

Signature of participant: _____ Date: _____

Please PRINT participant name: _____

Signature of Investigator: _____ Date: _____

Please PRINT investigator name: _____



Consent Form [Investigator Copy]

1. I _____, agree to participate in the study described in the participant information statement set out above.
2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
4. I understand that I can withdraw from the study at any time without prejudice to my relationship to either Prince of Wales Hospital or Macquarie University.
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6. I understand that if I have any questions relating to my participation in this research, I may contact Dr Lindsey Brett, who will be happy to answer them.
8. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Support Office, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, email SESLHD-RSO@health.nsw.gov.au ;

Signature of participant: _____ Date: _____

Please PRINT participant name: _____

Signature of Investigator: _____ Date: _____

Please PRINT investigator name: _____

10.3. DATA COLLECTION SHEET

Variable	Source
MRN (only for code key to identify patients that complete the follow-up questionnaire and/or attend the clinic multiple times during the study, will not be included in the data extraction form used for analysis)	Falls, balance and bone health clinic attendance list/outpatient clinic file/electronic Medical Records
Unique study ID number	Assigned by researchers
Falls, balance and bone health clinic attendance date	Outpatient clinic file/electronic Medical Records
Referral source	Outpatient clinic file/electronic Medical Records
Year of birth	Outpatient clinic file/electronic Medical Records
Gender	Outpatient clinic file/electronic Medical Records
Height (cm)	Outpatient clinic file
Weight (kg)	Outpatient clinic file
Body mass Index	Determined by researchers (using height and weight measurements)
Country of birth	Electronic Medical Records
Primary language spoken	Electronic Medical Records
Marital status	Electronic Medical Records
Suburb	Outpatient clinic file/electronic Medical Records
Comorbidities	Outpatient clinic file/electronic Medical Records
Clinical investigation results	Outpatient clinic file/electronic Medical Records
Medications	Outpatient clinic file/electronic Medical Records
Montreal Cognitive Assessment score	Outpatient clinic file
Rowland Universal Dementia Assessment Scale score	Outpatient clinic file
Use of glasses	Outpatient clinic file
Mobility	Outpatient clinic file
Functional ability	Outpatient clinic file
Home environment	Outpatient clinic file
Who patient lives with	Outpatient clinic file
Support services used	Outpatient clinic file
Previous fractures	Outpatient clinic file
Smoking and alcohol history	Outpatient clinic file
DEXA results	electronic Medical Records
Vitamin D levels	electronic Medical Records

Variable	Source
Calcium levels	electronic Medical Records
Dietary intake	Outpatient clinic file
pQCT results	electronic Medical Records
Quickscreen ¹¹ total score/number of falls-related risk factors (count)	Outpatient clinic file
Probability of falls in next 12 months (%)	Outpatient clinic file
Five times sit to stand time (sec)	Outpatient clinic file
Falls History (previous 12 months)	Outpatient clinic file/electronic Medical Records
Low contrast vision acuity test result (numbered level)	Outpatient clinic file
Tactile sensation test result (pass/fail)	Outpatient clinic file
Semi-tandem stand (eyes open) time (sec)	Outpatient clinic file
Alternate step time (sec)	Outpatient clinic file
Timed Up and Go time (sec)	Outpatient clinic file
10m walk time (sec)	Outpatient clinic file
Gait speed (m/sec)	Determined by researchers (using 10m walk test result)
Falls Efficacy Scale – International score	Outpatient clinic file
Attitudes to Falls-Related Interventions Scale score	Outpatient clinic file
Recommendation from falls, balance and bone health clinic	Outpatient clinic file/electronic Medical Records
Hospitalisation date of admission	Electronic Medical Records
Hospitalisation reason for admission	Electronic Medical Records
Hospitalisation length of stay (days)	Electronic Medical Records

10.4. DATA EXTRACTION FORM

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	
13	Comorbidities																						
14	Clinical investigations																						
15	Meds.																						
16	MoCA																						
17	RUDAS																						
18	Use of glasses																						
19	Mobility																						
20	Functional ability																						
21	Home environment																						
22	Who lives with																						
23	Services/support																						
24	Previous #																						
25	Smoke																						
26	Alcohol																						
27	DEXA																						
28	Vit D																						
29	Calcium																						
30	Dietary intake																						
31	pQCT																						
32	QS total																						
33	5STS (QS)																						
34	Falls Hx (QS)																						
35	Vision (QS)																						
36	Sensation (QS)																						
37	Semi-tandem stand EO (QS)																						
38	Step test (QS)																						
39	TUG																						
40	10m walk																						
41	Gait speed																						
42	FES-I score																						
43	AFRIS score																						
44	Falls clinic recommendation																						
45	Hospitalisation date																						
46	Hospitalisation reason for adm.																						
47	Hospitalisation LoS																						
48																							
49	*BMI: body mass index, meds.: medications, MoCA: Montreal Cognitive Assessment, RUDAS: Rowland Universal Dementia Assessment Scale, #: fracture, Hx: history, QS: QuickScreen, 5STS: five times sit to stand, EO: eyes open, TUG: timed up and go,																						
50	adm.: admission, FES-I: falls efficacy scale – international, AFRIS: attitudes to falls-related interventions scale, LoS: length of stay																						
51																							