Research Study Protocol Template

1. Researcher details	
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2. Study Information and overview	
2.1 Study details	
Study title	Exploratory Study on the Prevalence of Sarcopenia-Causing Medicines in Patients with Sarcopenia and Falls
Study classification *(i.e. Research/Service Evaluation)*	Research
Department *(Please state where the study will be conducted & the name of the departmental manager)*	Falls clinic Lead Falls Clinician: Dr V Paranjyothi
Protocol Version Number *(Please state version number e.g. 1, 2)*	4
Protocol Version Date *(Please date protocol)*	20/7/25 IRAS ID: 354863. Approved: 31/7/25
2.2 lay overview of the project *Please provide an overview of the project in lay (non-scientific/no jargon) language. This overview should be understandable to most people.*	

Sarcopenia, characterised by the loss of muscle mass and function, is a prevalent condition among the elderly and is often associated with increased risk of falls. Certain medications, such as glucocorticoids, statins, and some antipsychotics, may exacerbate sarcopenia, leading to a higher incidence of falls. This study aims to explore the prevalence of such medicines in patients diagnosed with sarcopenia who have experienced falls. Understanding the impact of these medications on sarcopenia and fall risk can inform clinical guidelines and improve patient outcomes

2.3 Background/Literature review

Please provide any relevant background information to support the research area/disease. The subtitles below are to help guide you on what is required within this section. Please include published findings, Add full reference to the Reference List (Section 11). The Knowledge and Library Services can assist with completing a literature search and horizon scan please by visiting Request a Search - Medway NHS KLS

Overview of General Area

Sarcopenia, defined as the progressive loss of skeletal muscle mass and strength, is a significant contributor to adverse outcomes in older adults, including falls, frailty, functional decline, institutionalisation, and mortality (Cruz-Jentoft et al., 2019). The European Working Group on Sarcopenia in Older People (EWGSOP2) recognises low muscle strength as the primary indicator of sarcopenia. The prevalence of sarcopenia increases with age, affecting 10–27% of adults over 60 years and over 50% of those aged 80 and above (Shafiee et al., 2017). Similarly, falls affect one in three individuals aged 65 and over annually (WHO, 2021), and are a serious complication of sarcopenia. Evidence shows that sarcopenic individuals are 1.5 to 2.3 times more likely to fall (Landi et al., 2012).

Both sarcopenia and falls share multiple risk factors, one of the most important being medication use. Polypharmacy is prevalent among older adults and is associated with both increased fall risk and sarcopenia (Landi et al., 2019; Zia et al., 2017). Several classes of medications - including glucocorticoids, statins, loop diuretics, antidiabetic agents, and centrally acting drugs are known to exacerbate muscle loss, impair physical performance, or reduce mobility (Schakman et al., 2013; Scott et al., 2016; Fox et al., 2014). Despite this, the prevalence of such medications in older adults who have both sarcopenia and a history of falls has not been well defined. This gap limits targeted medication reviews and deprescribing strategies in high-risk individuals.

Prior research has established links between polypharmacy and adverse musculoskeletal outcomes, and systematic reviews have reinforced these findings (Tanskanen et al., 2015; Veronese et al., 2020). However, few studies have investigated the intersection of medication use, sarcopenia, and falls within clinical settings such as falls clinics. While falls services often focus on fall-risk-increasing drugs (FRIDs), little attention has been given to medicines that may worsen muscle health. Given that falls clinics routinely assess high-risk older adults and conduct comprehensive geriatric assessments, they offer a unique and practical setting for studying the prevalence and potential impact of sarcopenia-promoting medications.

This study aims to address this critical gap by evaluating the prevalence of medications associated with sarcopenia in older adults attending a falls clinic who have a diagnosis of sarcopenia and/or a history of falls. It will identify the most frequently prescribed drug classes with known muscle-impairing

properties and examine any associations between these medications and the severity of sarcopenia or falls risk. The results will contribute to the evidence base informing deprescribing strategies, medication review protocols, and falls prevention efforts in older adults.

Ultimately, this study has the potential to improve clinical outcomes and prescribing safety. It will offer practical applications for clinicians, including developing personalised deprescribing plans, enhancing clinical guidelines, and supporting safer prescribing in geriatric and falls services. On a broader level, it aligns with public health goals to reduce healthcare costs, support independent living, and improve the quality of life for older populations through optimised medication use.

2.4 Aims & Objectives

• Please insert a detailed description of the objectives and the purpose of the study.
• Please include a specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the study.
Objectives must be SMART
S: Specific
M: Measurable
A: Achievable
R: Relevant
T: Time bound

Aim: To determine the prevalence and types of medications associated with increased risk of sarcopenia among patients attending a falls clinic over a 6-month period.

Objectives:

1. To describe the proportion of older adults (aged ≥65) attending a falls clinic over a 6-month period that are prescribed one or more medications known to increase the risk of sarcopenia (e.g., glucocorticoids, statins, sedatives, anticholinergics).
2. To describe which sarcopenia-associated medication classes are most frequently prescribed in this cohort, and how many medications per patient fall into this category.
3. To assess the association between the number of sarcopenia-promoting medications prescribed and sarcopenia (as defined by clinical criteria such as grip strength, gait speed, or SARC-F score) in this population during the 6-month study period.
4. To describe the demographic and clinical characteristics of patients with sarcopenia and falls history who are on these medications including age, sex, ethnicity, history of previous falls and medical history.

2. Methodology *Please provide information as to how the study will be conducted; to include where/how and by who the data will be collected and analysed, the proposed duration of the study etc. The subtitles below are to help guide you on what is required in this section.*

Study Design:

This study will employ a cross-sectional observational design to determine the prevalence and patterns of medications known to increase sarcopenia risk among older adults attending a falls clinic over a 6-

month period. Cross-sectional studies are well suited for estimating prevalence and exploring associations at a single point in time, particularly in clinical populations (Levin, 2006).

Study Setting:

The study will be conducted in a multidisciplinary falls clinic at Medway NHS Foundation Trust, based in Gillingham, Kent. This secondary care setting receives referrals primarily from inpatient hospital teams and primary care practitioners. The clinic routinely assesses older adults who have experienced falls or are at high risk of falling, and conducts comprehensive geriatric assessments, including medication reviews, functional status evaluations, and frailty assessments (NICE, 2013). This makes them an appropriate setting for identifying medication-related contributors to sarcopenia and fall risk.

Study Period:

Data will be collected over a 6-month period (August 2025 to January 2026), enabling a sufficient sample while ensuring feasibility within available resources.

Study Population:

The study will include adults aged 65 years and older who attend the falls clinic during the 6-month data collection period. Sarcopenia will be assessed using validated tools such as the SARC-F questionnaire and physical performance measures (Cruz-Jentoft et al., 2019).

Inclusion criteria:

- Aged ≥65 years
- Attendance at the falls clinic for a new assessment
- Diagnosed with sarcopenia (based on the EWGSOP2 criteria)
- History of falls in the past 12 months

Exclusion criteria:

- Cognitive impairment preventing consent
- Acute medical instability
- Enrolled in on other clinical trials.

Sample Size Calculation:

The estimated prevalence of sarcopenia-promoting medications among older adults who fall, varies across studies due to differences in definitions, populations, and settings. Although no single study has reported the exact prevalence of sarcopenia-promoting medicines in older adults with both sarcopenia and a history of falls, multiple studies suggest a high burden of such medications in these populations.

While some studies conducted in hospitalised or long-term care populations report prevalence rates exceeding 50% (Corsonello et al., 2019), community and outpatient falls clinic populations generally exhibit lower rates. For example, Rawle et al. (2018) identified anticholinergic medication use in approximately 24% of community-dwelling older adults, and Reeve et al. (2014) reported that 30–70% of older adults who fall are prescribed medications associated with increased fall risk, with the lower range more applicable to outpatient settings. Considering the study setting is a falls clinic, where patients are typically community-dwelling and potentially less frail than hospitalised cohorts, an estimated prevalence of 30% for sarcopenia-promoting medicines is a conservative and evidence-based choice. This estimate ensures an appropriate balance between statistical rigour and resource feasibility for the exploratory study.

Assuming an estimated prevalence of sarcopenia-promoting medications of 30% among older adults attending the falls clinic, with a 95% confidence level and a margin of error of 5%, the calculated sample size for an infinite population is 323 participants. This calculation is based on Cochran's sample size formula for proportions, which is appropriate for large populations (Cochran, 1977).

Using the standard formula for an infinite population:

$$n = \frac{Z^2 \cdot p(1-p)}{e^2}$$

where:

- **Z** = 1.96 (for 95% confidence level)
- **p** = 0.30 (estimated prevalence)
- **e** = 0.05 (margin of error)

Calculating:

$$n = \frac{(1.96)^2 \cdot 0.30 \cdot (1-0.30)}{(0.05)^2}$$

$$n = \frac{3.8416 \cdot 0.30 \cdot 0.70}{0.0025}$$

$$n = \frac{3.8416 \cdot 0.21}{0.0025}$$

$$n = \frac{0.806736}{0.0025}$$

$$n = 322.7$$

Rounding up:

$$n \approx 323$$

Allowing for an estimated 10% rate of non-consent or dropout—consistent with participation rates reported in outpatient and community-based studies involving older adults (Toon et al., 1992) the effective sample size to account for this will be 359 participants. Despite this, it is estimated that around 500 patients will attend the falls clinic over a 6-month study period, based on current clinic throughput.

The recruitment period increases the likelihood of obtaining a representative sample. The end of the study is defined as the date on which the final data point is collected from the last participant or the completion of any follow-up data collection required, whichever occurs later.

Sampling Method:

A consecutive sampling approach will be used to include all eligible patients attending the falls clinic during the study period. Although non-probabilistic, this method is commonly used in clinical settings to ensure timely recruitment and adequate sample size (Etikan et al., 2016).

Data Collection Methods

Study Instrument:

Data will be collected using a standardised spreadsheet from routinely recorded clinical information in the Electronic Prescribing and Medicines Administration (EPMA) system and patient health records. Clinical assessments will include:

- SARC-F questionnaire for sarcopenia screening,
- Rockwood Clinical Frailty Scale (CFS) to assess for frailty,
- Grip strength, Timed-Up and Go test (TUGT), and gait speed for objective physical performance,

The European consensus on definition and diagnosis of sarcopenia (Cruz-Jentoft et al., 2019) highlights the above tools to diagnose sarcopenia. SARC-F is recommended to be used because its inexpensive and a convenient method for sarcopenia risk screening by the self-administrations of a five-item questionnaire. Grip strength is used to assess muscle strength and is a strong predictor of poor patient outcomes. It is moderately associated with strength in other body compartments and so it serves as a reliable surrogate for measures of arm and leg strength. Gait speed and the TUGT are commonly used in falls clinics to assess for functional mobility, and they have been shown to be predict adverse outcomes related to sarcopenia.

Medication data will be extracted from the EPMA system and categorised using British National Formulary (BNF) classifications to identify drugs associated with muscle impairment.

Study Implementation:

Potential participants will be identified through routine clinical attendance at the falls clinic within the study period. Screening will be conducted by doctors in the falls clinics who will review patient records and medication lists to identify individuals meeting the inclusion criteria. Eligible patients will be approached by doctors working in the falls clinic, who will introduce the study and provide the participant information sheet in lay language. This approach integrates seamlessly with standard care, minimising additional burden.

Consenting will be conducted face-to-face during the same clinic visit. The falls clinicians will ensure that potential participants have ample opportunity to ask questions and fully understand the purpose, procedures, risks, and benefits of the study. Written informed consent will be obtained prior to any data collection. For patients who require additional time to decide, arrangements will be made to revisit consent at a subsequent visit or via telephone within the study period, ensuring voluntary participation without coercion.

All study procedures, including data collection related to demographic information, clinical characteristics, medication use, and sarcopenia assessments, will be performed as part of or immediately following the routine clinical evaluation. This strategy ensures minimal disruption to patient care while maintaining rigorous data quality. The research team will maintain strict confidentiality and data protection throughout the study, in line with institutional and regulatory guidelines.

Quality of Data:

To ensure reliability and accuracy, the primary researcher will review all completed data sheets against source documentation. A 10% random sample will be independently audited by a second clinician to

confirm data accuracy and consistency. The spreadsheet will be formatted with built-in checks to minimise entry errors and missing data. Any discrepancies will be resolved by consensus or with senior clinical input.

2.7 Primary Measures

The primary outcome measure is the outcome that an investigator considers to be the most important among the many outcomes that are to be examined in the study.

3. Statistics

4.1 Planned statistical analysis

All data will be entered and analysed using Microsoft Excel. Statistical analysis will primarily involve descriptive statistics to summarise the prevalence and patterns of sarcopenia-associated medication use among older adults attending a falls clinic.

1. Descriptive Analysis
   a) Categorical variables (e.g. sex, sarcopenia status, medication classes) will be summarised using frequencies and percentages.
   b) Continuous variables (e.g. age, number of medications) will be reported as means and standard deviations or medians and interquartile ranges, depending on data distribution.
   c) The primary outcome - prevalence of sarcopenia-promoting medications - will be calculated with proportions and 95% confidence intervals, using Excel's statistical functions.
2. Exploratory Multivariate Analysis (if feasible)
   a) Python may be used to explore relationships between medication use and factors such as sarcopenia status, age, or number of falls.
   b) Any such analysis will be exploratory and interpreted with caution due to software limitations.

4.2 Person performing the statistical analysis?

The data will be anonymised, stored securely, and analysed by the principal investigator and the Senior Research and Innovation Project Facilitator at Medway hospital using password-protected Excel files and Python. A second reviewer will verify a random sample of the data for accuracy and consistency.

4. Risks and benefits

5.1 Risks of study participation

This study poses minimal risk to participants as it involves secondary analysis of data collected during routine clinical care. No additional procedures, tests, or interventions will be introduced. The primary risk pertains to data confidentiality. All data will be effectively anonymised and securely stored in accordance with NHS Trust data governance policies to mitigate any potential breaches of privacy.

5.2 Benefits of study participation

There are no direct benefits to individual participants. However, the findings from this study may inform future prescribing practices and improve medication safety for older adults at risk of sarcopenia and

falls. The results could also contribute to more targeted medication reviews and deprescribing strategies within falls services.

5.3 Risk Assessment performed?

A risk assessment will be undertaken as part of the set-up of this project and submitted to the Medway R&I team.

5. Data protection

Please describe how the data will be collected per the General Data Protection Regulation (GDPR). Include details of procedures for data handling, record keeping and archiving arrangements both during and post-study, including the location of data, accessibility rights and security provisions.

Data Handling and Anonymisation

Data will be extracted from routinely collected clinical records, including the Electronic Prescribing and Medicines Administration (EPMA) system and patient health records, as part of standard falls clinic assessments. This will include information on medications, frailty scores, physical performance measures (e.g., grip strength, gait speed), and adjusted BMI.

All data collected during the study will be handled in accordance with the Data Protection Act 2018 and General Data Protection Regulation (GDPR) to ensure participants' privacy and confidentiality. Personal identifiable information (PII) will be collected only as necessary for recruitment, consent, and linkage of clinical data.

Upon collection, identifiable data will be securely stored on encrypted NHS Trust computers accessible only to authorised members of the research team. Each participant will be assigned a unique study ID number, and all subsequent data analysis will use these anonymised ID codes to prevent identification of individuals.

Hard copies of consent forms and any paper records will be stored in locked filing cabinets within secure NHS facilities. Electronic data will be password protected with access restricted to study personnel. Data transfer, if required, will be conducted using secure, encrypted methods.

Anonymised datasets used for analysis and publication will contain no direct identifiers. Only aggregated data will be reported, ensuring individual participants cannot be identified. Data retention will comply with institutional policies, storing research data securely for at least 5 years post-study completion.

Data Storage and Accessibility

During the study, all data will be stored on Trust-approved encrypted systems within Medway NHS Foundation Trust's secure IT environment. Only the primary researcher and supervising clinicians with data access approval will be permitted to view the study dataset. Data will not be transferred outside the Trust's systems without appropriate approvals.

Archiving and Retention

Upon study completion, anonymised research data will be archived securely for a minimum of 5 years in accordance with Medway NHS Foundation Trust research governance policy and Good Clinical

Practice (GCP) standards. Identifiable data (if retained for audit purposes) will be securely destroyed following the retention period, in line with Trust data destruction protocols.

Security Provisions

- Data will be stored on encrypted drives with multifactor authentication.
- Regular backups will be performed on secure Trust servers.
- No data will be saved to personal devices or removed from NHS premises.

Ethical and Governance Oversight
This study will be conducted in accordance with the principles of the Declaration of Helsinki and applicable national regulations governing research involving human participants. Ethical approval will be sought and obtained from a Research Ethics Committee (REC) prior to study commencement. The study will also be reviewed and approved by the relevant Health Research Authority (HRA) and Medway NHS Trust research and innovation (R&I) departments to ensure compliance with governance standards.

All research personnel involved in the study will have completed appropriate Good Clinical Practice (GCP) training and will adhere to institutional policies for patient safety, confidentiality, and data protection. Regular monitoring by the Medway R& I team, and audit activities will be implemented to ensure adherence to the approved protocol, regulatory requirements, and quality standards.

6. Funding
7.1 Does this project require funding?
No
7.2 Has funding been secured
n/a
7.3 Have you completed a study budget
n/a

7. Ethical considerations
Please list any factors of your project that may lead to ethical issues.
This study involves the use of routinely collected clinical data from older adults attending a falls clinic at Medway NHS Foundation Trust. Although no additional interventions will be introduced, ethical approval will be sought from the Health Research Authority (HRA) and an NHS Research Ethics Committee (REC), given the study's use of identifiable clinical information for research purposes. All participants will receive a written participant information sheet outlining the study's purpose, the voluntary nature of participation, and how their data will be used and protected. Written informed consent will be obtained prior to inclusion. Patients will be informed that declining participation will not affect their current or future clinical care. To ensure data confidentiality, all information extracted for the study will be anonymised at the point of analysis. No directly identifying information will be included in the research dataset. All data will be

stored on encrypted NHS Trust servers, with access restricted to authorised personnel only. All members of the research team will complete GCP training.

8. Dissemination plans

Please list all the ways you plan to share the findings of this project. This may include scientific journal publications, conference presentations etc.

The findings of this study will be disseminated internally within Medway NHS Foundation Trust via clinical governance meetings, audit reports, and engagement with the falls clinic and pharmacy teams. Externally, results will be submitted for presentation at relevant academic and professional conferences such as the British Geriatrics Society (BGS) and for publication in a peer-reviewed journal (e.g. *Age and Ageing*, *Drugs & Aging*). A lay summary of the findings will be made available to patients and carers through clinic communications and the Trust's website. The study aims to inform safer prescribing and medication review practices for older adults, contributing to falls prevention strategies and local guideline development.

9. Any other relevant information

10. Reference List

Please add in full references you have added into text in the above sections. Use Harvard referencing style (For examples see link https://www.scribbr.co.uk/referencing/harvard-style/). If your field has a selected referencing style use that one.

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