Statistical Analysis Plan (SAP)

Shoes for self-managing Chronic HIP Pain: the SCHIPP randomised clinical trial

Contents

Section 1. Administrative Information

1. Title

Shoes for self-managing chronic hip pain: the SCHIPP randomised clinical trial

2. Trial registration

Prospectively registered (Australian New Zealand Clinical Trials Registry Trial Id: ACTRN12621001532897, 21/09/2021)

3. SAP version

Version: 1.0 Date: 3-Dec-24

4. Protocol Version

This document has been written based on information contained in the SCHIPP study protocol version 1.0 dated 17/06/2021. The protocol was published as follows:
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5. SAP Revisions

Not applicable

6. Names and affiliations

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Section 2: Introduction

7. Background and rationale

Chronic hip pain is a highly prevalent condition that is largely due to osteoarthritis (OA). Hip OA affects around 40 million people globally and is a leading cause of years lived with disability.[1] With an ageing population and rising rates of obesity, the condition is projected to increase by 58% in Australia over the next decade, leading to substantial societal and health care burden.[2] Pain and stiffness are hallmark signs of hip OA,[3] and these contribute to difficulties performing simple daily activities such as sitting and walking,[4] which in turn adversely affects quality of life.[5] These symptoms are also major determinants for invasive and costly end-stage hip joint replacement surgery.[6] As a consequence, OA has been designated a National Health Priority Area in Australia.

As hip OA has no cure, advice on self-management of symptoms is recommended as a core treatment component for all patients with hip OA.[7, 8] International OA guidelines advocate clinicians provide advice about "appropriate" footwear for self-management of hip OA symptoms,[7, 9] based on expert opinion because hip joint loading is influenced by foot motion.[10] While optimal footwear is likely to be of considerable importance for people with hip OA, there are no clinical trials of footwear in people with chronic hip pain that can inform clinicians about which shoe types are best to manage symptoms in these people. As a result, leading international OA bodies such the National Institute for Health Care Excellence in the United Kingdom,[7] the American College of Rheumatology[8] and the European League Against Rheumatism[9] have all called for research to determine optimal footwear for patients with OA as a leading research priority. Currently, guidelines advocate 'stable supportive' shoes for people with OA based solely on expert opinion, yet no research has investigated whether stable supportive shoes are effective at reducing symptoms in people with chronic hip pain. Due to the relative dearth of research in people with hip OA relative to knee OA, these organisations have also called for well-powered studies to evaluate the effect of non-pharmacological treatments specifically in people with hip OA.[9]

8. Objectives

Research hypothesis:

Primary alternative hypothesis: That stable supportive shoes will lead to significantly greater reductions in hip pain with walking at 6 months, compared to flat flexible shoes.

Secondary alternative hypothesis: That stable supportive shoes will have significantly greater benefits on other clinical outcomes (other parameters of hip pain, symptoms, physical (daily living) function, sport and recreation function, hip-related quality of life, pain at other sites, global improvement in pain, achieving a clinically-relevant reduction in pain, adverse events, and physical activity levels) compared to flat flexible shoes at 6 months.

Study objective:

Primary objective: To determine if stable supportive shoes lead to significantly greater reductions in hip pain during walking compared to flat flexible shoes when worn over six months, in people with chronic hip pain consistent with OA.

Secondary objective: To determine if stable supportive shoes will have greater benefits on other clinical outcomes (other parameters of hip pain, symptoms, physical (daily living) function, sport and recreation function, hip-related quality of life, pain at other sites, global improvement in pain, achieving a clinically-relevant reduction in pain, adverse events, and physical activity levels) compared to flat flexible shoes when worn over 6 months.

Section 3: Trial Methods

9. Trial design

A two-arm pragmatic, comparative effectiveness, parallel-group randomised controlled trial. Treatment allocation is a 1:1 ratio. Participants are randomised to either stable supportive shoes or flat flexible shoes.

10. Randomisation

Eligible participants will be randomised according to a 1:1 allocation ratio to receive either stable supportive or flat flexible shoes. The randomisation schedule will be prepared by an independent biostatistician (permuted random block sizes). The schedule will be stored on a password-protected website (REDCap^{TM}) maintained by a researcher not involved in either participant recruitment or administration of primary/secondary outcome measures. Group allocation will be revealed by this same researcher after baseline primary/secondary outcomes have been completed.

11. Sample size

We aim to detect the minimal clinically important difference (MCID) between groups of 1.8 (out of 10)[11] numerical rating scale (NRS) units in change in hip pain intensity during walking (baseline minus follow up). We have assumed a conservative between-participant standard deviation across all participants of 2.7 units and a conservative correlation between baseline and 6-month scores of 0.20, based on our previous trial.[12] Using analysis of covariance (ANCOVA) adjusted for baseline score, we need 48 per arm to achieve 90% power to detect the MCID in change in pain at a 0.05 significance level. Allowing for 20% attrition, we will recruit 60 people per arm (n=120 in total).

12. Framework

This trial uses a superiority hypothesis testing framework between groups for all outcomes.

13. Statistical Interim analyses and stopping guidance

Nil

14. Timing of final analysis

Final analysis will be performed after all (n=120) participants have reached the 6-month timepoint and have been provided with the opportunity to complete outcome assessments, and after the Statistical Analysis Plan has been finalised and published on our Centre's website.

15. Timing of outcome assessments

Primary and secondary outcomes were collected at baseline, where relevant, and 6 months post-randomisation (primary end-point) and continuous outcomes measured at baseline were derived as changes (baseline minus 6 month follow up). The timing of each outcome assessment is summarised below. A detailed description of each outcome can be found in Section 26 and Appendix 1.

Name	Time-points measured
Primary Outcome	
Severity of hip pain during walking	Baseline & 6 months

Secondary Outcomes	
Hip disability and Osteoarthritis Outcome Score (HOOS) Pain subscale	Baseline & 6 months
HOOS symptoms subscale	Baseline & 6 months
HOOS function in daily living subscale	Baseline & 6 months
HOOS function in sport and recreation subscale	Baseline & 6 months
HOOS quality of life subscale	Baseline & 6 months
Pain severity at the following sites: a) Contralateral hip b) Ipsilateral knee c) Contralateral knee d) Ipsilateral foot/ankle e) Contralateral foot/ankle f) Back	Baseline & 6 months
Achievement of a clinically relevant reduction in walking hip pain	6 months
Global rating of change (achievement of global improvement in pain)	6 months
Adverse events (experience of at least one)	6 months
Physical Activity Scale for the Elderly (PASE) score	Baseline & 6 months

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Section 4: Statistical Principles

16. Level of statistical significance

The primary outcome was powered for and will be assessed using a 5% significance level, with the p-value for the difference in means specified to three decimal places. All other outcomes are exploratory so decisions about the intervention effect on these outcomes will not be based on $p<0.05$. All estimated effects will be presented with corresponding 95% confidence intervals and p-values displayed to three decimal places.

17. Description of any planned adjustment for multiplicity, and if so, including how the type 1 error is to be controlled

There is only one primary outcome so no multiplicity adjustment is required for the primary analysis. We have numerous secondary outcomes. All secondary outcomes are exploratory and not powered for. We will therefore not adjust for multiple secondary outcomes but instead report the estimates, confidence intervals, and p-values in order to let readers use their own judgment about the relative weight of the conclusions regarding the intervention group effects on secondary outcomes. This approach aligns with the usage of p-values favoured by the American Statistical Association.[13]

18. Confidence intervals to be reported

All confidence intervals will be two-sided 95% confidence intervals.

19. Adherence and Protocol Deviations

The primary analysis will be based on the principle of intention-to-treat, whereby participants are included in the groups to which they were originally assigned, regardless of their adherence to their assigned intervention. Any protocol deviations (if they occurred), including errors applying inclusion/exclusion criteria and/or administration of the wrong intervention, will be summarised in trial results (patient flow diagram/text) by treatment group. Randomisation errors resulting from these errors will be handled according to recommendations.[14]

Multiple measures of adherence are used in this trial (described below as well as in Table 4.6 of the protocol and Appendix 1 of the statistical analysis plan). Data from all measures will be reported using means and standard deviations (or medians and interquartile ranges, if skewed) and proportions (number and percentage) as appropriate for each treatment group.

In this study, participants are advised to wear their allocated shoes for at least 6 hours per day. Participants will rate their level of compliance with the task of wearing their study shoes for a minimum of 6 hours per day each day on average over the previous 6 months using an 11-point NRS (where 0=shoes not worn at all and 10=shoes worn completely as instructed). The average and standard deviation will be reported per group, with higher scores indicating better adherence. Participants will also be classified as adherent to the intervention (or not) based on the log-book data recording daily allocated shoe wear (hours per day). Participants complete one log-book per month for a 7 day period (snapshot), reporting the number of hours each day that they wore each of their two pairs of allocated shoes. The hours reported for each pair of shoes will be summed for each reported day to give a daily total. The daily total will be averaged over the 7 days for each of the six reporting periods (months). The mean (standard deviation) hours/day of wearing allocated shoes will be reported for each month of the six months across treatment groups, as well as for the entire 6-month intervention period. The number (%) of adherent (defined as average daily shoe wear $\geq$ 6 hrs) and non-adherent (average daily shoe wear < 6 hrs) participants will be reported for each treatment group at each month over the six months as well as for the entire 6-month intervention period.

If a participant does not provide all log-books, average daily allocated shoe wear will be calculated using the

available log-books. If a participant does not provide any log-books, non-adherence will be assumed.

The number of participants who stopped wearing the study shoes will also be reported. Participants will indicate whether they stopped wearing the study shoes during the 6 months (Yes or No). Participants who score Yes will describe when and why they ceased wearing their allocated shoes, and this will be reported descriptively.

20. Analysis Populations

The primary analysis will be based on the principle of intention-to-treat, whereby participants are included in the groups to which they were originally randomised, regardless of their adherence to their assigned treatments.

Section 5: Trial Population

21. Screening Data

Screening data will be collected and summarised. A CONSORT flow diagram will be used.[15] The following summaries will be presented in text and/or flow diagram: time frame for recruitment, the number of participants screened, the number of participants recruited, the number of screened participants not recruited, and the reasons for non-recruitment.

22. Eligibility

Trial inclusion and exclusion criteria are summarised below. Reasons for exclusion will be summarised in the CONSORT flow diagram.[15]

Participants were eligible for the study if they met the following inclusion criteria:

i) National Institute for Health and Care Excellence working definition of peripheral joint OA[7]:
   a. aged ≥45 years;
   b. activity-related hip joint pain; and
   c. either no morning hip joint stiffness or stiffness that lasts no longer than 30 minutes;
ii) report history of hip pain of at least 3 months duration;
iii) report hip pain on most days of the past month;
iv) report a minimum hip pain score of 4 out of 10 on an 11-point NRS (terminal descriptors of 0='no pain' and 10='worst pain possible') during walking over the previous week.

Participants were ineligible for the study if they met one of the following exclusion criteria:

i) diagnosed in the past 12 months by a health professional as having gluteal tendinopathy, greater trochanteric pain syndrome, referred hip pain from the lumbar spine or femoro-acetabular impingement syndrome;
ii) hip replacement on the most painful side;
iii) recent hip surgery (past 6 months) or planned surgery in next 6 months;
iv) current use of shoe orthoses, customized shoes or brace (on any joint of lower limb);
v) current regular use of high heels, thongs or work boots that would restrict ability to wear allocated trial shoes 6 hours/day;
vi) had any hip injection in the past 3 months or planning an injection in next 6 months;
vii) self-report other muscular or joint condition anywhere in the body which is worse than study hip pain;
viii) self-report any systemic or inflammatory joint disease (e.g., fibromyalgia, rheumatoid arthritis, gout);
ix) any neurological condition affecting the spine or either lower limb;
x) current or planned use of a gait aid in the next 6 months;
xi) inability to understand written/spoken English; and
xii) unable to commit to study requirements (e.g., wearing shoes, attending appointments, completing outcomes, do not have foot size in the range of 8 to 13US for men, and 7 to 12US for women).

23. Recruitment

A CONSORT flow diagram[15] will be used to describe the number of people enrolled, randomised, allocated to each treatment group, lost to follow up (including reasons) and analysed.

24. Withdrawal/follow-up

If a participant withdraws from the study, the nature, timing of and reasons for withdrawal will be described (provided the participant responds to contact made by the research team). Any data provided up to the point of withdrawal will be analysed in accordance with intention-to-treat analyses, unless the participant specifically

requests to withdraw their data from the study. Losses to follow-up (including reasons) will be summarised in the CONSORT flow diagram by treatment group.

25. Baseline characteristics

Baseline characteristics will be summarised by treatment group and presented in a table:

- Age
- Gender
- Ethnicity
- Height, body mass, body mass index
- Duration of hip pain symptoms
- Current employment status
- Education level
- Unilateral hip pain symptoms
- Expectation of treatment outcome (before randomisation/shoe allocation)
- Co-intervention use including medications
- Comorbidities
- Presence/absence of chronic widespread pain
- Objective measures of foot posture including:
    - Foot posture index
    - Foot mobility magnitude
    - Navicular drop
- Footwear characteristics of the most commonly worn pair of own shoes, reported as the number and proportion of participants who currently use flat flexible shoes, stable supportive shoes and/or shoes of mixed features.

Although the protocol describes baseline measures of in-shoe plantar pressures and ground reaction forces while walking, this data will not be described in the trial report as it is complex biomechanical data that is not measured in typical clinical practice (thus does not influence interpretation of trial findings) and is not going to be used in the planned moderation analyses. Instead, this data will be reported in a separate paper.

Baseline characteristics will be summarised as appropriate (means and standard deviations for continuous variables that appear to be distributed approximately symmetrically, medians and interquartile ranges for other continuous variables, counts and percentages for categorical variables). Tests of statistical significance will not be undertaken for comparing baseline characteristics of treatment groups; rather the clinical importance of any imbalance will be noted.

Section 6: Analysis

26. Outcome definitions

Primary outcome:

- Change in severity of hip pain during walking: Average overall hip pain on walking in the past week was self-assessed using a 11-point NRS with terminal descriptors of 'no pain' (score 0) and 'worst pain possible' (score 10). Change score at 6 months will be calculated as baseline minus follow-up.

Secondary outcomes:

- Change in each of pain, symptoms, function in daily living, function in sport and recreation, and quality of life in the last week: The five subscales of the Hip disability and Osteoarthritis Outcome Score (HOOS) were measured including i) pain (10-items), ii) symptoms (5-items), iii) function in daily living (17-items), iv) function in sport and recreation (4-items), and v) quality of life quality of life (4-items). Responses are provided on a 5-point scale. Scores will be transformed for each subscale and range from 0 to 100 with 0 indicating worst possible symptoms. Change scores at 6 months will be calculated as baseline minus follow-up.

- Change in average overall pain severity over past week at other sites: i) contralateral hip, ii) ipsilateral knee, iii) contralateral knee, iv) ipsilateral foot/ankle, v) contralateral foot/ankle, vi) back, were each scored on an 11-point NRS for average overall pain in the last week. Scores range from 0 to 10; where 0='no pain' and 10='worst pain possible'. Change scores at 6 months will be calculated as baseline minus follow-up.

- Achievement of a clinically relevant reduction in walking hip pain: Classified based on individual change in walking hip pain (primary outcome), where anyone who achieved a pain reduction greater than or equal to the MCID of 1.8 NRS units is classified as achieving a clinically-relevant pain reduction.

- Adverse events (experience of at least one): Defined as any problem experienced in the study hip or elsewhere in the body deemed by the participant to be a result of participating in the trial AND at least one of i) caused increased pain and/or disability for two days or more, and/or ii) resulted in the participant seeking treatment from a health professional. These were self-reported by participants using a custom-developed table. Whether participants experienced any adverse event or not will be compared between groups.

- Global improvement at 6 months: Scored using a 7-point global rating of change Likert scale with response options ranging from "much worse" to "much better" when compared to baseline. Participants who indicated they were "moderately better" or "much better" will be classified as 'improved'. All other respondents will be classified as 'not improved'.

- Change in physical activity: The Physical Activity Scale for the Elderly was used to assess physical activity over the previous week. This is a 10-item questionnaire which collects responses for the frequency, duration and intensity level of a range of activities typically chosen by older adults. Scores range 0 to >400 (1177 is maximum) with higher scores indicating greater levels of physical activity. Change scores at 6 months will be calculated as baseline minus follow-up.

27. Analysis methods

Primary outcome:

Main comparative analyses between groups will be performed using intention-to-treat. If fewer than 5% of participants have missing primary outcome data at 6 months, then the primary analysis method will be a complete case analysis, involving participants with complete data at baseline and follow-up. If more than 5%

of participants have missing data at 6 months, multiple imputation will be used as the primary analysis method. A complete case analysis will be conducted in secondary analysis. For the primary outcome, differences in mean change in walking hip pain will be compared between groups using a linear regression model, adjusted for baseline values.

Secondary outcomes:

Continuous secondary outcomes will be analysed using similar approaches to the primary outcome, with adjustment for baseline values where measured. For binary outcomes, groups will be compared using risk ratios and risk differences, using logistic regression models. Adverse events will be analysed as a binary outcome (whether at least one adverse event was experienced) using logistic regression, as per other binary outcomes, and not Poisson regression, as stated in the published protocol[16] since few participants experienced more than one adverse event. Standard diagnostic plots will be used to check model assumptions.

28. Statistical Methods – adjustment for covariates

For the primary hypothesis, differences in mean change in pain (baseline minus follow-up) will be compared between groups using linear regression modelling adjusted for baseline values. A secondary sensitivity analysis will estimate treatment effects of wearing stable supportive shoes compared to flat flexible shoes on the primary outcome adjusted for the presence of chronic widespread pain in addition to baseline values of the primary outcome.
For continuous secondary outcomes, linear regression models will also be adjusted for baseline values. For the binary/other outcomes, regression models will not be adjusted.

29. Statistical Methods – sensitivity analyses

As a deviation to the published protocol,[16] we will no longer conduct a sensitivity analysis to estimate treatment effects of wearing stable supportive shoes compared to flat flexible shoes on the primary outcome with a complier average causal effect analysis, as assuming not wearing stable supportive shoes is equivalent to wearing flat flexible shoes is no longer considered a reasonable assumption. A secondary sensitivity analysis will estimate treatment effects of wearing stable supportive shoes compared to flat flexible shoes on the primary outcome adjusted for the presence of chronic widespread pain in addition to baseline values of the primary outcome.

30. Statistical Methods – subgroup analyses

To assess whether the effect of stable supportive shoes on the primary outcome is moderated by either of the pre-specified moderators of (baseline) BMI or foot posture index score (continuous variables), interaction terms between randomised group and each of these variables will be included in regression models for the primary outcome at 6 months, for each potential effect modifier separately. The rationale for the *a priori* choice of treatment effect modifiers is as follows:

- BMI- we hypothesise that decreases in hip pain with stable supportive shoes (relative to flat flexible shoes) will be greater in people with a higher BMI, given that these people have a greater vertical loading rate compared to lower BMI adults,[17] and thus have greater scope for a reduction in loading rate with stable supportive shoes.
- Foot posture- we hypothesise that decreases in hip pain with stable supportive shoes (relative to flat flexible) will be greater in people with a more pronated foot posture, given stable supportive shoes are designed to reduce foot pronation, and foot pronation is associated with lower limb pathology.[18]

As a deviation to the published protocol,[16] we will not assess whether the effect of stable supportive shoes on shoe comfort is moderated by foot posture index. Shoe comfort is not considered as a secondary outcome in this study. Subgroup analyses will only be considered for the primary outcome.

31. Missing data reporting and assumptions/statistical methods to handle missing data

If more than 5% of participants are missing the primary outcome at 6 months, an appendix table will provide summaries as appropriate (means and standard deviations for continuous variables that appear to be distributed approximately symmetrically, medians and interquartile ranges for other continuous variables, counts and percentages for categorical variables) of the participant characteristics and levels of the primary and secondary outcomes at baseline, as well as treatment group. This will enable assessment of whether the characteristics are similar between those participants who provide the primary outcome at 6 months and those participants who are missing the primary outcome at this time-point, to assess the assumption that data are missing completely at random (MCAR). Tests of statistical significance will not be undertaken for comparing those with complete and incomplete 6-month primary outcome data; rather, the clinical importance of any imbalance will be noted.

If more than 5% of participants are missing the primary outcome at 6 months, multiple imputation will be applied as the primary analysis method, with complete case analysis used as the secondary analysis method. The number of imputed datasets will be approximately equal to the proportion of participants missing the primary outcome, with a minimum of 20 imputed datasets created if the percentage missing is between 5% and 20%. Missing baseline characteristics will be imputed using single mean imputation. Missing outcome values will be imputed separately by treatment group, using chained equations and predictive mean matching, using the five nearest neighbours. Imputation models will include baseline levels of all outcomes, where relevant, and all baseline characteristics. Initially imputation models for all outcomes will be chained together, with outcomes broken into subsets if imputation models do not converge. Imputed datasets will be compared to complete data using density plots for continuous outcomes and plots of proportions for binary/other outcomes.

To assess the potential impact of the violation of the missing-at-random assumption on conclusions for the primary outcomes should multiple imputation be used as the primary analysis, a pattern-mixture approach (as in White et al [19]) will be applied. We will explore the impact of the violation of the missing-at-random assumption if the assumption was violated in both groups, or in one group only.

32. Additional Analyses

Nil

33. Harms

Adverse events were defined as “any problem experienced in the study hip or elsewhere in the body deemed by the participant to be a result of participating in the trial AND at least one of i) caused increased pain and/or disability for two days or more, and/or ii) resulted in the participant seeking treatment from a health professional”. Adverse events were self-reported by participants using a custom-developed table at 6 months. We will report the nature, number and proportions of participants experiencing adverse events by treatment group. A serious adverse event will be defined as any untoward medical occurrence that; i) results in death; ii) is life-threatening; iii) requires hospitalisation or prolongation of existing inpatients hospitalisation; iv) results in persistent or significant disability or incapacity; v) is a congenital anomaly or birth defect, or; vi) any other important medical condition which, although not included in the above, may require medical or surgical intervention to prevent one of the outcomes listed.

34. Statistical Software

Stata v18 will be used (StataCorp. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC)

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