**Question 1**

To estimate the population prevalence of heel pain (HP) in the United Kingdom (UK), a cross-sectional study will be performed. The proposed study will also assess the impact of HP on daily activity, identify factors associated with HP, determine health-seeking behaviors towards HP, and discover available treatments.The study will require 2 years for completion (Figure 1) and will be completed in two phases. Phase 1 of the study will be the distribution and collection of a questionnaire to patients ≥18 years old registered at a local medical facility. From the completed questionnaires, 75 individuals with HP will be selected for examination by a podiatrist in Phase 2.

The study will be submitted to the Ethics board in January 2017 with the expectation that approval will be granted in 2 months. Upon approval, protocol and questionnaire development and approval will span 5 months. The protocol and questionnaire will be developed by the general practitioner (GP), who is serving as the primary researcher, alongside research assistants. The hiring and training of the staff will require 4 months. The GP and senior research personnel will recruit, select, and train the appropriate staff. Data collection and data entry, which includes the distribution of questionnaires, will span a total of 10 months and these tasks will be performed by research assistants. Once the data has been collected, subsequent analysis will require 4 months, and report writing and documentation will account for the final 2 months of the study (Figure 2). Additional staff members will include data analysts who will work with de-identified data, and a board certified podiatrist and registered nurse(s) who will complete Phase 2 of the study. Final documentation and report writing will be performed jointly by the analysts and the GP’s research team.

During Phase 2 of the study, the 75 selected individuals will undergo a structured interview conducted by a nurse to gather information on self-treatment and health seeking behavior, as well as lifestyle choices such as physical activity. Patients will also be asked to identify the location of their heel pain using a manikin. Finally, the patients will be scored using the Manchester Foot Pain and Disability Index (MFPDI). The MFPDI is a self-administered, paper based patient reported outcome consisting of 19-items assessing foot pain and disability. The assessment contains 3 social constructs which are functional limitation, pain intensity, and personal appearance. Responses are recorded on a three point scale consisting of “None of the time”, “On some days”, and “On most /every day(s)”. The MFPDI will therefore provide information on the extent to which HP affects daily activity.



**Figure 1**. Gantt chart showing the amount of time required to complete each stage of the proposed cross-sectional study. Critical stages are colored in red and less critical stages are colored in blue.

**Question 2**

The objective of the study is to determine the prevalence of HP, therefore it is necessary that a representative sample is drawn from the population. To ensure that the study is sufficiently precise and supplies the power to reject a false null hypothesis, an appropriate sample size will be chosen. The questionnaire will be mailed to a simple random sample of patients who are registered at the medical practice. Since the patient registry is complete and informative with measures such as age, body weight, and comorbidities it will serve as an appropriate sampling frame. To avoid underrepresentation of subgroups, the sampling frame will be stratified by age and sex. The sampling frame will be divided into age strata of 18–30 years, 31–49 years, 50–64 years, 65–74 years, and ≥75 years and different sampling fractions will be applied to each stratum with the largest fraction used on the smallest stratum. This will allow the estimates of HP among the strata to be more precise for robust statistical inference and interpretation. Patient age was selected as the criterion for stratification, because it is unclear whether age is associated with risk of posterior HP in adults ([Chatterton et al., 2015](#_ENREF_1)), despite the fact that the fat cushion in the heel begins to degenerate after the age of 40 ([Rosenbaum et al., 2014](#_ENREF_2)). Simple random sampling (SRS) will be conducted computationally by random digit generation. First, the patients in the sampling frame will be numbered from 1 to 10,000. Then randomizing software will be used to assign random IDs to the patients, and the age-sex stratified random sample will be drawn.

Since nonresponse could become a major pitfall of the study, the questionnaire will be designed in a user-friendly format. Patients will be asked to shade the region of the foot where they feel pain on a manikin. Patients will also receive follow-up phone calls within 3 weeks after the questionnaires have been mailed to them. Since non-responders could bias the results of the study, a profile of illnesses and other related characteristics for the non-responders will be constructed by the GP. This profile will be compared to the profile of the responders to better interpret the results of the study. During data analysis, weighting will be used to reduce the statistical bias introduced by the non-responding population of questionnaire recipients.

**Question 3**

The prevalence of HP will be calculated as a proportion of the responder population using the number of patients with HP as the numerator, and the number of patients without HP as the denominator. This prevalence estimate will then be weighted to account for selective nonresponse from the baseline sample. Weighted logistic regression with age and sex as covariates will be used to determine the population level prevalence estimates and corresponding 95% confidence intervals (95% CIs).

Univariate logistic regression will be used to calculate the odds ratios (ORs) and 95% CIs between HP and age, sex, and BMI, individual occupational class, and physical activity level to detect associations between HP and the aforementioned factors. These factors have been chosen because increasing BMI and manual occupations have been shown to be a risk factor for posterior HP ([Chatterton et al., 2015](#_ENREF_1)), while physical activity has been reported to be protective ([Chatterton et al., 2015](#_ENREF_1)). The results of these analyses will be presented in tables as well as box-and-whisker plots that show differences between the genders if they are detected.

Patient reports of self-treatment and health-seeking behavior will be collected and scored using Likert type scales. The scores will be used as outcome measures in factorial analysis using analysis of variance (ANOVA) with adjustments for possible confounders such as age, sex, and comorbidities. All statistical analyses will be performed using R statistical software.

**Question 4**

Biased results may result from the data generated due to inappropriate sample size, sampling method, and nonresponse. To address sampling error, an adequate sample size will be used, and SRS will be conducted using age and sex strata. This will minimize the under-sampling or oversampling of subgroups within the population, while generating a sample that is more representative of the general population. Nonresponse bias will be addressed by first calculating the prevalence among responders, and then calculating a weighted prevalence using the information available for non-responders. This will ensure that the calculated prevalence is more generalizable to the population at large.

**Question 5**

The proposed study design will allow the estimation of the prevalence of HP in the UK. It will also provide insightful information on patient risks and behaviors alongside the development of HP. HP prevalence among subgroups such as gender and age will also be provided by the study. For GPs, information regarding self-treatment and health-seeking behaviors will be provided. Finally associations between HP and gender, BMI, physical activity, and individual occupation will be determined. The current study is therefore suitable for public health planning, and for assisting GPs and podiatrists with the provision of care and services for patients with HP.

The limitations of the study include an inability to infer causality between the associated risk factors, restriction to a single time-point, and a lack of incidence measures. Without measures of incidence risk factors associated with death will be under-represented among patients who complain of HP. An alternative approach would be a long-term multicenter, ongoing study that follows individuals over time. A prospective study of this nature would allow the identification of common factors that promote or diminish the risk of developing HP.

**References**

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