Usability and Acceptability Study of the P-STEP Mobile Application

NCT05830318

9th April 2026

Protocol and Statistical Analysis Plan

INTRODUCTION

Background

Lifestyle changes such as increasing physical activity levels can greatly reduce the risk of mortality for people with long-term conditions (LTCs)[1]. Exercise is crucial to health and it is recommended that an individual does a minimum of 150 mins moderate intensity exercise per week[2]. Despite the benefits of regular physical activity, many patients living with LTCs, such as asthma, COPD, heart disease, remain inactive and do not meet current guidelines[3, 4].

Air pollution is an important factor for patients with LTCs, and can severely impact those suffering from cardiac and respiratory diseases[5, 6]. There is a risk of exacerbating symptoms when exercising outdoors, if air quality is poor, which may be leading to physical inactivity in some patients. Many patients live in fear of worsening symptoms and therefore minimise their exposure to air pollution by remaining indoors[1].

Mobile phone applications (apps) are becoming increasingly used to help to support those with LTCs, including advice on behavioural change such as increasing activity levels. Many apps also exist to provide information on air quality. To date, no app has been developed to combine these two related issues. The Personalised Space Technology Exercise Platform (P-STEP®) app brings together tailored exercise guidance, taking into account an individual's LTCs, while also providing up-to-date information on air quality. The app allows individuals to plan exercise routes in order to minimise their exposure to air pollution, by using the information to avoid higher polluted areas.

Research question

The purpose of this study is to assess the usability and acceptance of the P-STEP® app, by allowing participants with specific LTCs to pilot the app for a 12-week period. We will also assess the feasibility of study design features and outcome measures, which will help inform a future clinical trial.

METHODS

Design

The study design will take the form of a single arm 12-week app pilot study based in Leicestershire, United Kingdom (UK). Questionnaire data will be collected at three timepoints, baseline, 6 weeks and 12 weeks. Weekly anonymised usage data from the app will also be collected by the app team. We will recruit a maximum of 380 participants to pilot the app for 12 weeks. This study has been approved by the South West Frenchay Research Ethics Committee (REC), who confirmed there is no need for further Health Research Authority (HRA) approval. The adapted SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) checklist for reporting the protocol of a pilot study has been included in supplementary information **Table S2**[7-9]. The SPIRIT figure, which demonstrates the schedule of enrolment, interventions, and assessments is included in **Figure S1**[7].

Screening and Recruitment

Participants will be recruited from the Extended Cohort for E-health, Environment and DNA (EXCEED) cohort. EXCEED (REC ref 13/EM/0226) is a longitudinal population-based cohort study that facilitates the investigation of genetic, environmental and lifestyle-related determinants of a broad range of diseases and of multiple long-term conditions[10]. EXCEED participants have consented to be contacted about participating in other research studies. We are using the EXCEED cohort because we are focusing on recruiting participants with

particular LTCs, and EXCEED will give us access to these participants. For example, in 2019, the numbers of participants in EXCEED diagnosed with at least one of the conditions we require were as follows; asthma (n=1,138), heart disease (n=393), COPD (n=301), diabetes (n=826), and heart failure (n=107)[5]. The EXCEED team will identify participants and invite them to join the study, based on the following criteria:

- Adult ≥ 18 years
- Live in Leicestershire.
- Diagnosed with at least one of the following conditions*:
    - Asthma
    - Chronic obstructive pulmonary disease (COPD)
    - Interstitial lung disease (ILD)
    - Coronary heart disease (CHD)
    - Heart failure (HF)
    - Type 2 diabetes
- Do not have dementia, learning disability, mental health disorders (other than depression or anxiety), or epilepsy
- Are not receiving palliative care

*This criterion will be relaxed if recruitment is slower than anticipated.

The EXCEED research team will email potential participants who meet the above criteria with information about the P-STEP® pilot study and give them an individual link to a closed webpage. Potential participants will have the opportunity to read more about the study and register their interest through an MS Forms. Those who register their interest in the study will then be screened as to whether they meet the following additional inclusion criteria:

- Android smartphone which has access to the internet
- Can walk outside for a minimum of 5 minutes without feeling unsteady
- Available to pilot the app from June 2023 – January 2024
- Able to give informed consent to participate in the evaluation

And will be excluded if:

- English language restriction (it is made clear that documents and app are only available in English, and participants should only register if confident with this.)
- Advised not to do exercise by a health care professional, in the last 12 months.
- Access to an iOS smartphone only
- Diagnosed with dementia, learning disability, mental health disorders (other than depression or anxiety), epilepsy
- Receiving palliative care
- Pregnant
- Chest pain at rest
- Unsteady when standing or walking
- Current cancer patient
- Part of the P-STEP® User Engagement group

Study duration, data collection and follow up

Participants that meet the inclusion criteria will be invited to enrol on to the study, this includes going through a process of formal informed consent. The participant information sheet and consent form will be emailed to participants via REDCap, a secure web platform for collecting and managing online survey data[11, 12]. A copy of the consent form has been included in the supplementary information **Figure S2.** After participants have filled in the consent form, it will be checked and signed by a member of the research team. The participant will then complete the baseline questionnaire, which will also be sent via the REDCap system. The baseline questionnaire is s shortened version of the follow up questionnaire that asks only about participant demographics and characteristics, quality of life and physical activity levels. Questions about the app are then included at follow up. After returning the baseline questionnaire, participants will then be texted the link to download the app.

After participants have been given access, they will pilot the app for 12 weeks. Questionnaires will be sent out to participants for them to self-administer and complete at 6- and 12-week post baseline, via REDCap. Questionnaires administered and data collected will be the same at both the 6- and 12-week follow-ups. Separate from the questionnaires, objective usage data will be automatically collected by the app and returned to the app development team on a weekly basis. These data are anonymous and it is not possible to link this information directly to a participant. Table 1 displays the objective usage data we will collect for this study.

Table 1: Usage data

Usage information	**Rationale/use**
Number of downloads	Number of downloads will give us an idea of interest and the feasibility of administering the app. Successful downloads means the users have successfully clicked on the link and downloaded the app.
Number of logins	At the beginning stages of the study, we can compare this with number of downloads. Later in the study it will give us an idea of whether people log-out and come back to log-in or stay logged in the duration of the study.
Number of walks recorded	Number of physical activities recorded in a week.
Clicks on feature	Will give us an idea on how much each feature is used across participants.
Time spent on feature	Will give us an idea on how much each feature is used across participants.
Clicks on links to external sites	Will give us an idea on how much each links to external sources are used across participants.
Notifications delivered	Help us to identify how much notifications are enabled, how many clicks from notifications we get, can identify if there is a surge in use after a notification has been received.
Number of log outs	Idea on behaviours such as whether users log in/log out, stay logged in, stay logged out.

Number of app uninstalls	Idea as to how many users do not like the app, therefore delete during the study period
Device/model the app has been installed on	Feasibility of app on different devices

Patient and public involvement (PPI)

Members from the University Hospitals Leicester NHS Trust Lifestyle PPI group, and members from the EXCEED cohort (described below) have been involved in the design of this pilot study. The PPI for this study included designing and reviewing the study documents such as the register your interest form, participant information sheet, informed consent form, baseline and follow-up questionnaires. PPI members were also included in reviewing the participant pathway to identify ways to minimise the burden to participants.

Peer Review for Ethics Approval

The protocol for this study was reviewed by two individuals, independent from the project and study team, prior to gaining Ethics approval. Both reviewers mentioned the need to consider multiple mitigation strategies to prevent potential high dropout. Multiple strategies were incorporated into the study, including giving participants the opportunity to be supported by a member of the study team when downloading the app, and setting up a helpline to encourage users to use if they are having any trouble with accessing/using the app.

Reviewer 2 commented on how many participants we are expected to recruit from each of the long-term condition (LTC) groups, and how many with a single LTC vs multiple LTCs. We will not be stratifying by LTC at the recruitment stage. This is because for feasibility reasons, we would like to see which LTC groups come forward and volunteer to pilot the app. As well as this, we expect a large proportion of patients to have multiple LTCs, given the nature of the EXCEED cohort, and will not be excluding participants for this.

Reviewer 2 requested a more detailed definition of “Usability”. This has been updated.

Reviewer 2 asked for the reason we are only recruiting from the EXCEED cohort for participants in this study. The reason for this is that we wanted to ensure we are recruiting participants with the six LTCs that we are interested in. The EXCEED cohort study group gives us direct access to these participant groups to help with recruitment.

Reviewer 2 commented on the long list of exclusion criteria, however, for any study involving physical activity, be it interventional or guidance, detailed exclusion criteria is required in order to ensure the maximum safety for participants.

Data analysis

Bias

Participants will be asked to provide informed consent and will be given detailed information on the structure of the study to ensure a full understanding.

To avoid user bias, we will exclude participants who are part of the P-STEP® User Engagement group as they have been involved in the design of both the app and the study. All participants that complete the baseline questionnaire will be included in the study and analysis.

Participants are being recruited only from the EXCEED cohort. We acknowledge that by recruiting only through EXCEED, we are recruiting individuals who sign up to be in a cohort

study (and therefore, have signed up to be a part of future research) which may not necessarily represent the general population.

We acknowledge that including only English-speaking participants may exclude certain groups, however, to date the app has only been developed in English and as this is a usability and acceptability study it felt this restriction is necessary.

Risks

Questions asked to participants will avoid areas of cultural sensitivity and will be focused around the participants' experience with the app. As we are also collecting some demographic information, data will be anonymised and handled in accordance with data protection procedures at the University of Leicester. Participants will be required to download and use the app onto their mobile phone, which they do so at their own risk after accepting the app terms and conditions. Use of the app may consume mobile data. It is recommended to participants for the app to be downloaded whilst connected to WIFI to avoid the use of mobile data. Participants will be provided with vouchers to compensate for any additional data usage incurred or purchased upon provision of receipts, up to a total of £20.

Sample size

As this is a pilot study, a formal power calculation has not been undertaken. Initial searches by the EXCEED team to estimate the population size for this study, given the first stage of inclusion criteria, is 1,525. Given the second stage of inclusion criteria, we estimate a maximum interest rate of 380. We will therefore recruit up to a maximum number of 380 participants. While this sample size is larger than other pilot studies, it has been reported in previous studies while testing the usability of apps, there are higher levels of dropouts (up to 80%), than other types of pilot studies[13]. Recruiting 380 participants with an 80% dropout rate would result in 76 participants completing the study. Previous studies[14, 15] in the space of assessing usability with the System Usability Scale have reached conclusions with a sample size of 20. General guidance[16-18] on feasibility studies suggests that a sample size of 30-50 participants is an adequate number to make conclusions for both the usability and feasibility outcomes. We believe this will be an adequate group to make conclusions on the usability of the app, as well as information to inform a future trial. Anyone that registers their interest after the deadline, or when the maximum is reached, will be thanked for their interest but told that recruitment is closed. The additional registrations of interest will be included in the feasibility outcomes.

Statistical Analysis

Baseline characteristics will be summarised using mean and standard deviation (SD) or median and interquartile range (IQR) for continuous variables and count and percentage/proportion for categorical. Each questionnaire will be scored and analysed using the methods described by the developers of the questionnaires. The primary outcome measure for this study is the System Usability Scale (SUS) at 12 weeks. The mean and standard deviation of the SUS, usability and user engagement scores will be reported at 6 and 12 weeks. A breakdown of responses to the SUS questionnaire will be tabulated. The SF-12 and RPAQ will be collected at baseline, 6 and 12 weeks. An indication of changes over time will be reported using a mixed effects model. Feasibility outcomes will be reported as a mean and standard deviation or count and percentage where appropriate.

All statistical analyses will be performed in Stata v17/BE.

Outcomes

Primary outcome measure

The primary outcome measure for this study is the System Usability Scale (SUS) at 12 weeks. The SUS is a validated and popular instrument for measuring perceived usability (8). There are 10 items in total, 5 with a positive tone and 5 with a negative tone. The responses range from strongly disagree to strongly agree. The original questionnaire asks about the "system" however it is acceptable practice to replace system with a relevant term such as website, or app, therefore this study replaces the word system with app. The SUS responses will be scored using the methods described by the developers of the questionnaire[19]. Each item's score contribution ranges from 0-4. For items 1,3,5,7 and 9, the score contribution is the scale position minus 1. For items 2,4,6,8, and 10, the contribution is 5 minus the scale position. The score is then multiplied by 2.5 to obtain the overall value of the SUS on a scale of 0-100. General guidance suggests a SUS score 68 and above considers the usability score to be above average and anything less below average[19]. The mean and standard deviation of the Usability scores will be reported at 6 and 12 weeks.

Secondary outcome measures

Usability Questions (P-STEP® specific)

Nine additional usability questions, detailed in **Table S1**, that relate specifically to the features of the P-STEP® app, will be asked at 6 and 12 weeks. These questions have had input in from our PPI group, and through a process of iteration we finalised nine questions on a Likert scale of strongly agree to strongly disagree. Individual items in the questionnaire will be tabulated with percentages. For example, 77% of participants strongly agreed that the app was suitable for their age group. The mean and standard deviation of the Usability scores will be reported at 6 and 12 weeks.

User Engagement Scale Short Form (UES-SF)

The User Engagement Scale - Short Form (UES-SF) is a reliable and valid questionnaire containing twelve items that measure user engagement (8). There are 12 items which are categorised into; focused attention, perceived usability, aesthetic appeal, and reward. The UES-SF responses will be scored using the methods described by the developers of the questionnaire (8). An overall user engagement is calculated by converting the score to a numeric value of 1-5 (strongly disagree equals 1, strongly agree equals 5) and taking the mean. The mean and standard deviation of the UES-SF scores will be reported at 6 and 12 weeks.

Quality of Life

The Short Form 12-Item Health Survey (9, 10) (SF-12) is a health-related quality of life tool that measures functional health and well-being from the participant's perspective. It assesses eight domains; physical functioning, physical role, pain, general health, vitality, social functioning, social role, mental health. SF-12v2 responses will be scored and interpreted using the SF-12v2 user guide (9). The 8 domains will generate two summary scores; physical component score (PCS) and mental component score (MCS). Scores for the PCS and MCS range from 0-100, and a higher score indicates a higher quality of life. The participant's quality of life will be calculated at baseline, 6 weeks and 12 weeks. An indication of change in quality of life over time will be reported using a mixed effects model.

Recent Physical Activity Questionnaire (RPAQ)

The Recent Physical Activity Questionnaire (11) (RPAQ). This questionnaire is designed to find out about a participant's physical activity in their everyday life. The RPAQ will be scored and interpreted using the scoring guidelines published by the authorsThe participant's

RPAQ score will be calculated at baseline, 6 weeks and 12 weeks. An indication of change in physical activity over time will be reported using a mixed effects model.

Usage Data & Feasibility Outcomes

Usage data will be extracted weekly by the app team. This information will give us an indication of the usage of the features of the P-STEP® app which will be used to inform the feasibility outcomes. The data extracted will be a summary of all participants, however this information is anonymous and therefore cannot be linked back to participants. Feasibility outcomes will be reported as count, mean, proportions or length of activities in minutes. The feasibility outcomes that will be reported are presented in **Table 2**. These outcomes will assess the feasibility of using certain study design features and outcome measures which will help plan a future trial for effectiveness.

The feasibility of recruiting through a cohort study (EXCEED) will be assessed through the interest outcome in the feasibility table. This will give an indication of whether recruitment through a cohort study for a future study would be feasible or if alternate strategies, such as recruitment through GP practices would need to be considered. We will also assess the interest in certain groups (for example with each of the conditions) and this will further inform how recruitment is structured moving forward to ensure specific groups are targeted if necessary.

Table 2: Feasibility outcomes

Feasibility outcome	**Measure**
Interest	Percentage of those eligible who register their interest.
Eligibility	Percentage of participants who register their interest that pass eligibility screening and enrol.
Enrolment	Percentage of those who pass eligibility who then go on to enrol on the study
Feasibility of administering the app	Percentage that successfully download the app. Percentage that are on boarded vs download independently.
Acceptability of the app	Percentage of participants who enrol and complete the 12-week study
Acceptability of outcome measures	Percentage of participants who complete baseline, 6 and 12 week follow up
Acceptability of online questionnaires	Percentage that require help to complete online questionnaires Percentage of withdrawals that give method of data collection as reason.
The proportion of screened participants ineligible and reasons for ineligibility	Number/proportion of participants screened and deemed ineligible

Adverse Events and Serious Adverse Events

Adverse events (AEs) and serious adverse events (SAEs) will be recorded in line with University of Leicester policy. Participants will be asked some additional health questions at week 6 and 12 that will allow us to report AEs/SAEs.

Long term clinical outcomes

Finally, we will gain consent from the P-STEP® participants for the data collected in this study to be transferred to the EXCEED study team. This will enable linkage to electronic health records (EHR) in the future and allows the EXCEED study team to analyse long term outcomes such as mortality, cardiovascular events. The primary data collected in this study, together with EHR records will allow the monitoring of long-term clinical outcomes.

Success criteria of the study

We expect to see above average usability scores and medium engagement, scoring at least 68 on the SUS and bespoke usability questionnaires and at least a 3 out of5 on all engagement domains for the User Engagement Scale Short Form. Questions worded negatively will be transposed such that 3 out of 5 on the User Engagement Scale has the same meaning for each response. The free text fields will allow participants to comment on the functionality of the app which can be taken forward to future iterations, prior to a full-scale trial. For the feasibility outcomes, we deem rates of over 85% as acceptable and will take forward those aspects of study design when planning a future trial. Anything less than this will be reviewed and addressed or removed as appropriate during the design of a future trial.

Missing Data

Participants that drop out will be encouraged to still complete the questionnaires. Participants that drop out between 6 and 12 weeks will be analysed using the available data (6-week responses). Where scoring guidelines from the above questionnaires have mentioned how to deal with missing data, these guidelines will be followed.

Data Management

Data Collection and Source Data Verification

Participants will receive a unique link to the questionnaires via email, at baseline, 6 weeks and 12 weeks and will be given a deadline to fill in the questionnaires. Copies of the fully signed consent form will be provided to the participant via email. A Data Management Plan will be created by the Project Management Group with specific details on data handling and record keeping. The usage dataset generated by the app itself will be stored securely. This data is collected weekly and summarizes users' interactions with the app.

Data Protection & Patient Confidentiality

Personal data included in study-related databases shall be treated in confidence and in compliance with ICH-GCP, the UK Policy Framework for Health and Social Care, the Data Protection Act 2018 (DPA 2018) and the EU General Data Protection Regulation (GDPR).

Data Access and Storage

All study documentation will be retained in a secure location during the conduct of the study. Personal identifiable data will be retained by the study team for a maximum of 12 months following the end of the study, after which it will be destroyed. Personal identifiable details such as names and contact details will be retained on a password protected database until required, and then destroyed. All electronic data will be stored on secure network systems, to which only the relevant study personnel will have access. The dataset will be anonymised and stored securely.

Ethics approval and consent to participate

This study has had ethical approval from the South West Frenchay Research Ethics Committee (REC 23/SW/0060). There is no need for further approval from the Health

Research Authority. Individuals will be required to give informed consent to participate in this research.

Consent for publication

As part of informed consent, participants will consent for the results to be published

Availability of data and material

Data is confidential and cannot be shared.

Competing interests

None

Funding

GA Ng was supported by a British Heart Foundation Programme Grant (RG/17/3/32,774) and the Medical Research Council Biomedical Catalyst Developmental Pathway Funding Scheme (MR/S037306/1). This study was supported by the National Institute for Health and Care Research (NIHR) Applied Research Collaboration East Midlands (ARC EM) and Leicester NIHR Biomedical Research Centre (BRC). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. The app is part funded by the European Space Agency **133105/20/NL/AF** and part funded by the University of Leicester. The study Sponsor is the University of Leicester (#0901).

Dissemination

Dissemination will be through peer review publication.

Registration

The ClinicalTrials.gov ID number is NCT05830318. Protocol Version 3, dated 20th August 2024. Trial Sponsor is available at rgosponsor@leicester.ac.uk.

Authors' contributions

HW is the lead author and wrote the manuscript. LG, SA, RH, TL and AN contributed significantly to the design of the study. All authors have approved the final draft.

Acknowledgements

None

Supplementary information

Table S1: Bespoke usability questionnaires

The app provided me with walking guidance I felt was specific to my needs
The app provided me with up-to date air quality information
The app motivated me to walk more
The app allowed me to plan my walking route
I feel that the app is suitable for my age group
The app allowed me to track my progress
The app reassured me it would keep my data protected
The app allowed me to show friends and family my progress
The walking guidance recommended to me matches my ability

Table S2: Adapted SPIRIT checklist for reporting the protocol of a pilot study

Item	**Item No**	**Description**	**Addressed (page number)**
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	11
	2b	All items from the World Health Organization Trial Registration Data Set	11
Protocol version	3	Date and version identifier	11
Funding	4	Sources and types of financial, material, and other support	11
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	11
	5b	Name and contact information for the trial sponsor	11
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	11
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	11
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3-5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4-5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	4-5
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	16

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
N/AAllocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	4

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	10
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	7-9
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	9
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	10
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	10
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	10
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	10-11
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	4-5, 10-11

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10-11
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	11
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	10
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g. via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	10-11
	31b	Authorship eligibility guidelines and any intended use of professional writers	11
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	10-11
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	17
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Figure S1: Schedule of enrolment, interventions and assessments

Timepoint	Enrolment	Allocation	12-week study duration	Close-out
Register interest	X			
Eligibility screen	X			
Informed consent	X			
Given access to app		X		
Baseline assessment			X	
6 week follow up			X	
12 week follow up			X	X

Figure S2: Informed Consent Form

IRAS ID: 31870

Participant Identification Number for this trial:

CONSENT FORM

Title of Project: Acceptability and Usability of the Mobile App P-STEP

Purpose of the study: The P-STEP application (app) is designed for people with long term conditions, to help deliver walking advice while also helping to minimise exposure to air pollution. The purpose of this project is to run a pilot study of the app. You will be asked to use to app for 12 weeks and then give us feedback on whether you think the app is user friendly. We will be asking for your feedback to improve the app.

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet dated 14/10/2022. (version0.3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐
3. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
4. I agree to the EXCEED cohort study team being informed of my participation in the study in order to access and share my electronic health records with the P-STEP team. ☐
5. I understand that the information held and maintained by the EXCEED cohort study team may be used to provide information about my health status. ☐
6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person seeking consent	Date	Signature

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