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Non-randomised feasibility study testing a primary care intervention to promote engagement in an online health community for adults with troublesome asthma: protocol

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ABSTRACT

Introduction In the UK, approximately 4.3 million adults have asthma, with one-third experiencing poor asthma control, affecting their quality of life, and increasing their healthcare use. Interventions promoting emotional/behavioural self-management can improve asthma control and reduce comorbidities and mortality. Integration of online peer support into primary care services to foster self-management is a novel strategy. We aim to co-design and evaluate an intervention for primary care clinicians to promote engagement with an asthma online health community (OHC). Our protocol describes a 'survey leading to a trial' design as part of a mixed-methods, non-randomised feasibility study to test the feasibility and acceptability of the intervention.

Methods and analysis Adults on the asthma registers of six London general practices (~3000 patients) will be invited to an online survey, via text messages. The survey will collect data on attitudes towards seeking online peer support, asthma control, anxiety, depression, quality of life, information on the network of people providing support with asthma and demographics. Regression analyses of the survey data will identify correlates/predictors of attitudes/receptiveness towards online peer support. Patients with troublesome asthma, who (in the survey) expressed interest in online peer support, will be invited to receive the intervention, aiming to reach a recruitment target of 50 patients. Intervention will involve a one-off, face-to-face consultation with a practice clinician to introduce online peer support, sign patients up to an established asthma OHC, and encourage OHC engagement. Outcome measures will be collected at baseline and 3 months post intervention and analysed with primary care and OHC engagement data. Recruitment, intervention uptake, retention, collection of outcomes, and OHC engagement will be assessed. Interviews with clinicians and patients will explore experiences of the intervention.

Ethics and dissemination Ethical approval was obtained from a National Health Service Research Ethics Committee (reference: 22/NE/0182). Written consent will be obtained before intervention receipt and interview participation. Findings will be shared via dissemination to general practices, conference presentations and peer-reviewed publications.

Trial registration number NCT05829265.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study assesses the feasibility and the methodological and practical challenges of implementing and evaluating a digital social intervention in primary care, which is a novel self-management strategy.
⇒ The use of a mixed-methods design allows 'complementarity' and 'triangulation' (eg, quantitative data, from multiple data sets, corroborated with qualitative data and vice versa), thereby comprehensively refining the intervention and thoroughly informing processes in the main trial to fill the evidence gap about efficacy and safety of digital social interventions in primary care.
⇒ The use of a recruitment survey, sent to a wide range of patients, enables the testing of attitudes towards the intervention in different ethnic and socioeconomic groups.
⇒ A limitation of the study is the small sample receiving the intervention in only one region of the UK.
⇒ Due to the focus of this study, the sample is highly selected (ie, recruitment limited to digitally skilled, English-speaking patients).

INTRODUCTION

In the UK, there are approximately 4.3 million adults with asthma. Up to one-third of them experience poor asthma control, with

approximately 121 000 visiting accident and emergency (A&E) departments and 93 000 being admitted to hospital each year. In addition, there are 6.3 million asthma-related primary care consultations annually.[1–3] Asthma-related mortality in the UK (more than 1150 deaths/year) is among the highest in Europe.[4] Overall, the suboptimal asthma control translates to approximately £1.1 billion annual costs for the British National Health Service (NHS). Adults with uncontrolled asthma symptoms are likely to experience psychological consequences, ranging from anxiety disorders to panic symptoms, as well as loneliness and loss of social connections.[5–7] Psychological symptoms and loneliness, in turn, negatively affect health-related outcomes, quality of life, self-efficacy and self-management, symptom burden and overall ability to function.[8] Living with asthma also increases the odds of acquiring additional co-morbidities.[9]

Asthma-related interventions in primary care settings have the potential to improve health outcomes. For example, an educational programme in primary care sites in Quebec (Canada) fostering self-management techniques among patients with asthma improved medication adherence, asthma knowledge and control and reduced number of prescriptions for antibiotics as well as unscheduled visits for respiratory problems.[10] Likewise, a systematic review of 105 randomised controlled trials reports that self-management interventions for asthma took place in primary care sites in 70% of the trials and resulted in reduced healthcare use (eg, hospital admissions and A&E visits) as well as enhanced quality of life.[11]

Interventions that specifically promote emotional and behavioural self-management have been found to improve asthma control, prevent the development of additional comorbidities and reduce mortality.[12–14] Despite the evidence on the benefits of self-management,[15] evidence is still lacking on the effectiveness of those interventions. The use of online health communities (OHCs) is becoming increasingly common among patients as a means of accessing lay advice and interacting with people with similar health problems (peers).[16] Literature suggests that online peer-to-peer support can foster the maintenance and expansion of relationships that support patients' independence, by empowering them to manage their own health and care and to develop coping strategies.[17–19] Although online peer support through OHCs has informally existed for some time, formally promoting the use of OHCs within primary care services is novel, and little is known about its potential, efficacy and safety.[20 21] Previous research suggests that clinicians, especially in primary care and through face-to-face sessions, are paramount in promoting engagement with digital interventions, as well as engagement in studies testing these interventions.[22 23]

Building on: (a) current evidence on digital social interventions; (b) our previous work on the Asthma+Lung UK (ALUK) OHC and (c) patient and public involvement (PPI) activities, we hypothesise that engagement with OHCs promoted by primary care clinicians can enhance the self-management of asthma and ultimately reduce the burden on healthcare systems and providers.[24–27] As part of a larger research programme,[28] our aim is to design, implement and evaluate an intervention, delivered by primary care clinicians, based on a structured consultation for adults with asthma to encourage engagement with the ALUK OHC.

The Asthma OHC of the ALUK charity[29] is a moderated platform, hosted by HealthUnlocked and has currently about 20 000 users. The moderation team involves specialist respiratory nurses employed by ALUK, administrators employed by HealthUnlocked and voluntary patient moderators (who are users of the OHC). Moderation involves identification and removal of inappropriate posts/language, thereby ensuring that advice offered within the OHC is safe and sound. The moderation process relies on moderators screening posts, OHC user reporting, and automatic algorithms spotting keywords. The ALUK nurse moderators are also responsible for posting advice/polls/surveys, responding to queries that have not been answered, and signposting users to appropriate resources. Highly active users ('superusers') are very important for the cohesion of the OHC and the diffusion of information and peer support. Users in the OHC can just read posts and resources and/or actively engage with other patients with asthma through public posts and/or one-to-one private messages.

In this protocol, we are presenting our plans for conducting a study to test the feasibility and acceptability of the intervention, and its evaluation, including recruitment strategies, uptake and retention, data collection procedures and ability to analyse and link different data sets. Findings of this feasibility study will ultimately inform the delivery of a randomised controlled trial to generate evidence-based knowledge about the effectiveness and safety of digital social interventions in primary care.

METHODS AND ANALYSIS

Study design

A non-randomised, mixed-methods, feasibility study will be conducted to test and refine our digital social intervention. The feasibility study will consist of four steps: questionnaire survey to identify and recruit eligible patients; intervention delivery; collection of follow-up outcomes and exit one-to-one interviews with a sample of patients and primary care clinicians (summarised schematically in figure 1). Conditional on successful completion of the feasibility study, we plan to undertake a full randomised controlled trial.

Participants

Target recruitment to the feasibility study of intervention implementation is 50 patients. Eligible patients will be identified and recruited via a questionnaire survey distributed to adults on the asthma register at selected general practices in North and East London (see 'Recruitment processes' section below).

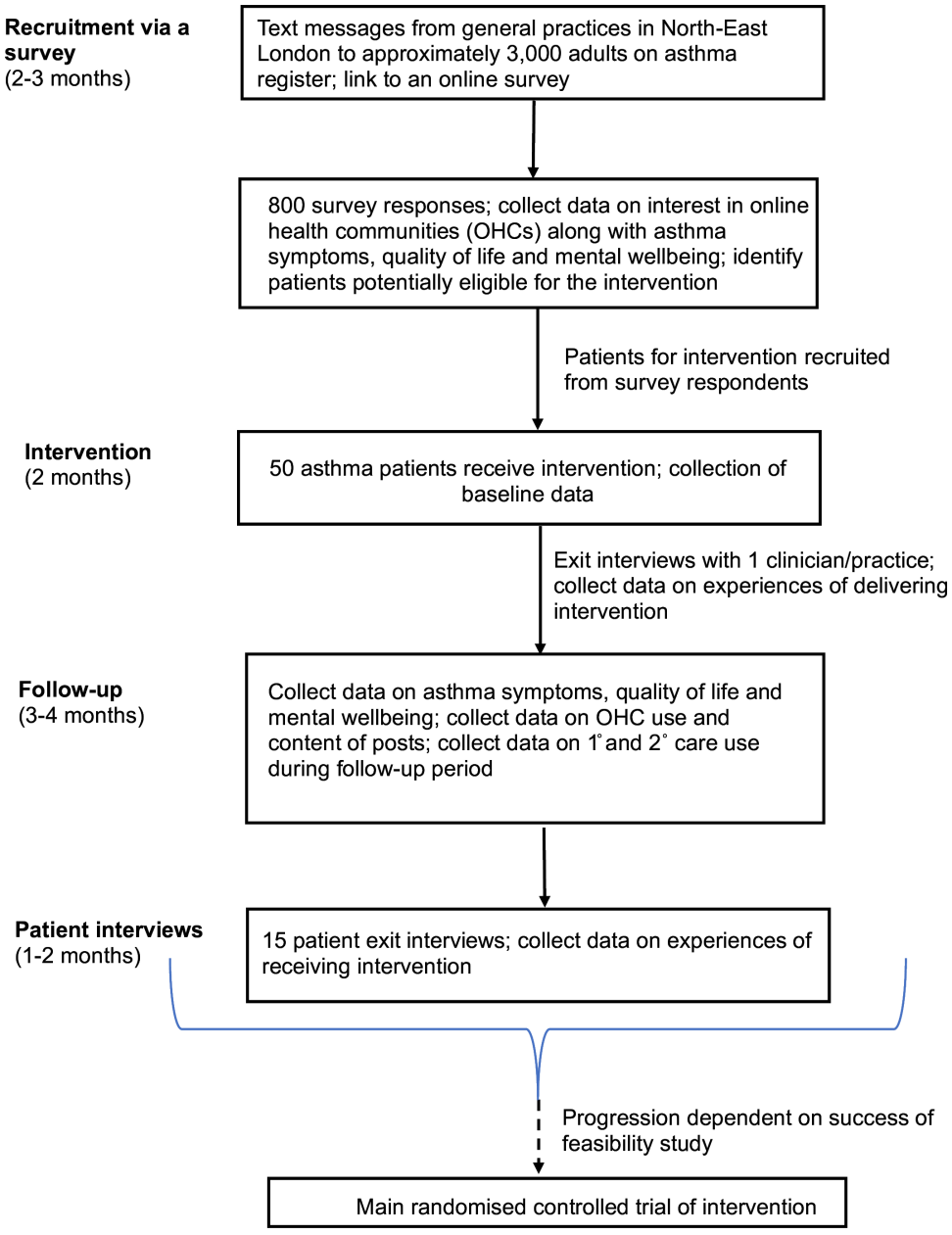

Figure 1 Flow diagram summarising the feasibility study process in the AD HOC research programme.

Eligibility criteria for receiving the intervention:

- Patients with an active diagnosis of asthma indicated in their online clinical records.
- Aged 18 years and above.
- Have expressed, in the questionnaire survey, interest in receiving a digital social intervention.
- Experience troublesome asthma (ie, asthma control test (ACT) score of less than 20), as expressed in the survey.
- Sufficiently fluent in English to participate in a consultation and subsequent data collection procedures, based on the knowledge of individual patients by practice staff and/or as determined at the time of inviting patients to receive the intervention.
- Have capacity to provide informed consent, as determined by a qualified primary care healthcare professional (see 'Consent' section below).

Exclusion criteria:

Patients who are:

- Receiving palliative or end-of-life care.
- Residents of care homes.
- Already a member of the ALUK OHC or other asthma OHCs/Facebook groups (not including general use of social media).

Recruitment processes

Six general practices in North and East London will be recruited with the assistance of the North Thames Clinical Research Network (CRN) of the National Institute for Health and Care Research (NIHR). Within each practice, clinicians who are willing to assist with recruitment processes and/or to deliver the intervention will be identified with the help of practice managers. Practices will receive funding for staff time invested in our study.

In each of these practices, a member of the direct care team will create a list of all potentially eligible adults from the practice asthma register. UK general practices have an asthma register, which lists patients with a diagnosis of asthma and a prescription for asthma-related drugs in the preceding 12 months (ie, patients with active asthma). These potentially eligible adults will initially receive a text message from their general practice inviting them to take part in an online survey, which will include a link to the online survey, and a link to the study's website with relevant documentation. Participants will be given 1 month to complete the survey and will receive a reminder text message 1 week before the survey's closing date.

Patients fulfilling the inclusion criteria will be identified via the survey and invited to receive the intervention. Eligible patients will be purposively sampled so that a range of ethnic/age groups, health literacy levels, ACT score ranges and co-existing conditions are represented in the cohort of patients receiving the intervention. Recruitment of survey respondents to the intervention will carry on until the target of 50 patients is achieved. Invitations to the intervention will be made via text messages from general practices. Convenient dates and times for intervention delivery will be established through direct communication between patients and staff at the general practices.

A subset of approximately 15 patients, purposively sampled in order to include a range of demographics, and all primary care clinicians who delivered the intervention will be invited, via a phone call/email from a member of the research team, to participate in an exit interview (ie, post intervention).

Study procedures

Questionnaire survey

The precise content of the online survey is currently under discussion with key stakeholders (patients, PPIs and primary care clinicians). However, we envisage including questions about participants' demographic and socioeconomic data, asthma symptoms, control and self-management, quality of life, mental well-being, health literacy and interest in digital social interventions (see online supplemental material 1 for a draft survey). Online survey completion and data capture will be undertaken using the Research Electronic Data Capture (REDCap) software, a secure application for designing and managing online surveys and databases. Completion of the survey is anticipated to take 10–20 min.

Intervention

Eligible patients identified through the survey will be invited to receive the intervention: a structured consultation with a primary care clinician (eg, a general practitioner (GP) or practice nurse or advanced clinical practitioner) to promote online peer support, followed by engagement with the ALUK OHC.

Dennis's conceptual model (ie, a theoretical framework referring to the development, measurement and evaluation of peer support interventions within healthcare)[30] has been used as a logic model in developing the intervention and hypothesising improvements in patient outcomes. Dennis's framework describes the key 'attributes' in peer support (namely emotional, informational and appraisal support, which relate to enhancing/restoring self-esteem, provision of information, and affirming the appropriateness of emotions/cognitions/behaviours, respectively) as well as the 'effect models' (see also data analysis section) through which beneficial outcomes are created and the required antecedents for peer support interventions (eg, selection of patients and clinician training). Data about clinicians' engagement with the online training will be collected (eg, completion rates, times accessed, etc). Figure 2 illustrates the composition of the intervention and training packages for clinicians, both of which are being refined collaboratively with various stakeholders.

Outcomes and measures

The primary outcomes of interest will be the key feasibility and acceptability parameters shown in table 1, assessed both quantitatively and qualitatively.

Secondary outcomes of interest will be those assessing the effectiveness of the intervention, both self-reported and non-self-reported. The self-reported outcome variables are shown in table 2 and will be collected via an online form again designed on REDCap software, at baseline and at 3 months following the intervention (this online data collection form is distinct from the earlier questionnaire survey). For the baseline collection, clinicians will add patients' responses to the online form at the intervention consultation. For the follow-up collection, participants will receive a link to the online form via a text message from their practice, for self-completion (should take 10–15 min).

In addition to the outcomes self-reported by patients, some additional outcome variables will be obtained, depending on data availability and consent being given for these variables to be extracted/recorded (table 3).

Exit interviews

Clinicians and a sample of patients will be invited to participate in a one-to-one, semi-structured interview (see 'Recruitment processes' section above for details on recruitment). Clinicians will be interviewed shortly after delivering the intervention to patients in their practice, whereas patients will be interviewed after the completion of the follow-up period. Members of the research team and/or members of the PPI group from the Asthma UK Centre for Applied Research (AUKCAR), appropriately trained in qualitative data collection techniques, will act as interviewers. An interview topic guide composed of open-ended questions and prompts (see online supplemental material 2) will be used to elicit experiences of delivering/receiving the intervention. Based on individual participants' preferences, interviews will take place either in person (within private spaces in the general practices)

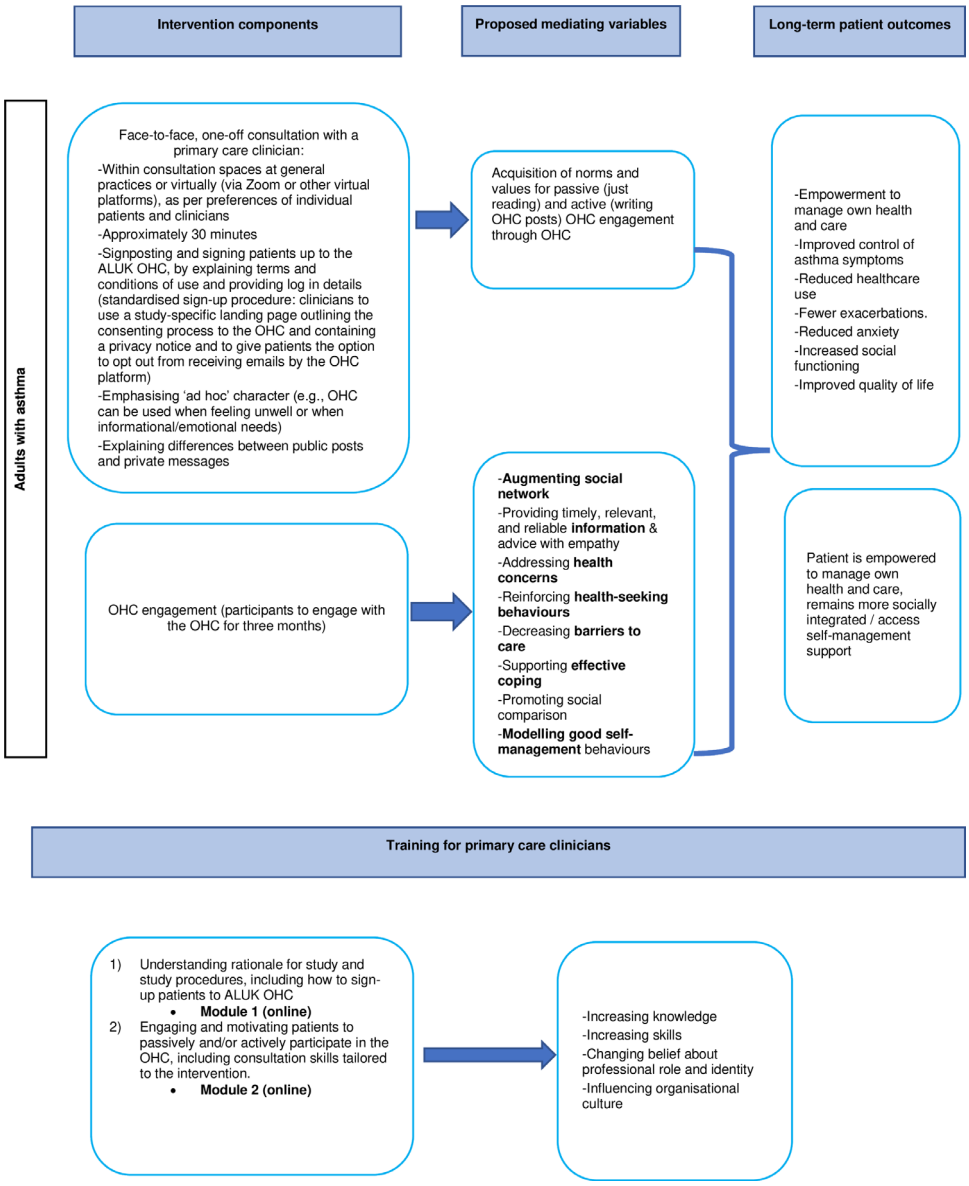

Figure 2 Logic model for the study intervention, along with training for clinicians delivering the intervention. ALUK, Asthma+Lung UK; OHC, online health community.

or virtually (via Zoom platform). Interviews should last up to 90 min and will be audio recorded through digital recorders or by using the Cloud function in Zoom. Basic demographic data will be collected from clinicians at the time of the interview.

Sample size justification

A sample size of 50 is considered adequate to estimate proportions (eg, uptake of digital intervention, follow-up rates) and other key summary statistics with informative 95% CIs in the context of a feasibility study. The sample size is not hypothesis driven since this is a feasibility study. The analyses represent an opportunity to demonstrate that the data collected can be used to reliably estimate parameters of interest in preparation for the main trial. To recruit 50 participants, we will invite approximately 3000 patients to complete the questionnaire survey. Response rates in online surveys are usually in the range of 25%–30%,[31] therefore, we anticipate 800 replies. We estimate that 25% of survey respondents will consider engagement with online peer support (ie, 200 people), since it is known that one in four people with long-term conditions goes online to find others with similar health concerns to seek peer support.[16] We further estimate that one-third of these will be eligible to receive the intervention (ie, 70 participants), as the percentages of adults with asthma who experience suboptimal asthma control range from 30% to 50%.[2 3] We have accounted for 70% of all eligible patients being available for recruitment, leading to approximately 50 patients receiving the intervention and providing follow-up measures. We are not accounting for any dropouts or losses at the follow-up period as part of the study is to test retention and provision of outcome measures at the follow-up.

Table 1 Outcomes relating to feasibility and acceptability of the intervention

Outcome	Data source
Number of patients on the active asthma register in the recruited practices	General practice records
Number and characteristics of:	
Survey respondents	Survey data
Patients willing and unwilling to receive the intervention	Survey data
Participants who withdraw or have missing data	Study database
Recruitment rate (ie, proportion of asthma register and/or survey respondents interested in and eligible for the intervention)	General practice records and survey data
Uptake rate (ie, proportion of eligible patients consenting to the intervention and/or actively or passively engaging in the online health community (OHC) for the duration of the study)	Survey data, study database and OHC activity data
Retention rate (ie, proportion of patients providing valid measures at the end of the follow-up period, see below)	Study database
Proportion of missing data (by outcome measure, see below)	Study database
Experience of patients and clinicians of receiving and delivering, respectively, the intervention	Qualitative, exit interviews (see below)

Data management

The Pragmatic Clinical Trials Unit (PCTU) at Queen Mary University of London (QMUL) will create a secure online database on REDCap for study data capture and storage. The survey questionnaire and data collection forms will be completed online, with data being stored directly in the database. Consent forms will either be completed online, or on paper with data being subsequently entered into the database and paper copies stored in locked filling cabinets at QMUL. Data extracted from the clinical records will be translated in electronic format and stored on a secure server at QMUL. Clinician demographic data collected at the exit interviews will be entered into the study database. Audio-recordings from exit interviews and electronic copies of transcripts will be stored on a secure server at QMUL. Records of the time taken to deliver the intervention along with lists of patients' emails used to sign up with the OHC will be stored on NHS password-protected computers and subsequently transferred to a secure server at QMUL. Participants' posts and activity on the ALUK OHC will be transferred by the OHC platform to a secure server at QMUL. Links between participation codes and participants' details will be stored on secure NHS computers at the practices and a QMUL server. All study data will only be accessible to members of the research team and will be retained in accordance with

Table 2 Outcomes and relevant measures, self-reported by participants

Domain	Outcome	Measure	Baseline*	3 months†
Clinical factors	Control of asthma	ACT questionnaire	X	X
	Adherence to medications	MARS-10 questionnaire	X	X
	Asthma exacerbations over last 3 months	Bespoke question	X	X
Quality of life	Health-related quality of life	EQ-5D-5L questionnaire	X	X
Economic factors	Primary and secondary care use over last 3 months	Bespoke question	X	X
	Time off work to seek care and/or due to asthma over last 3 months	Bespoke question	X	X
Psychosocial factors	Depression	PHQ-8 questionnaire	X	X
	Anxiety	GAD-7 questionnaire	X	X
	Self-efficacy	General Self-Efficacy Scale	X	X
OHC use factors	Amount and type (passive versus active) of OHC engagement	Bespoke question		X

*At the time of delivering the intervention.
†3months following intervention delivery.
ACT, Asthma Control Test; EQ-5D-5L, European Quality of Life 5 Dimensions 5 Level Version; GAD-7, Generalised Anxiety Disorder 7-item instrument; MARS-10, 10-item Medication Adherence Rating Scale; OHC, Online Health Community; PHQ-8, 8-item Patient Health Questionnaire depression scale.

Table 3 Non-self-reported outcomes of interest

Outcome	Data source	Baseline*	3 months†
Number of asthma exacerbations over last 3 months	Discovery‡ and/or NHS Digital§ and/or general practice records	X	X
Primary and secondary care health service utilisation and associated costs over last 3 months	Discovery and/or NHS Digital and/or general practice records	X	X
OHC engagement metrics (ie, amount of engagement, communities joined, number of logins, number of likes and time spent on pages), public posts and metadata (ie, time of post, thread and user details)	ALUK OHC data (provided by the manager of the OHC platform)		X
Time to deliver the intervention	Recorded by clinicians	X	

*At the time of delivering the intervention.
†3 months following intervention delivery.
‡Discovery is a clinical partnership project in East London to link primary and secondary care records, by creating a single database.
§NHS Digital is a national provider of health-related data setting out to transform and improve healthcare in the UK.
ALUK, Asthma+Lung UK; NHS, National Health Service; OHC, Online Health Community.

QMUL policies. Any processing and analysis of data will be done solely on QMUL, password-protected computers.

Data analysis plan

Qualitative and quantitative techniques, as well as methodologies from network sciences, will be used to analyse data. Qualitative data analyses will be facilitated by NVivo V.12 software,[32] whereas analyses of quantitative data will be carried out in Stata[33] and/or R software.[34] All data analyses will be performed collectively by the research team, employing the diverse expertise of different members accordingly.

Quantitative analyses

All survey replies will be collated and analysed using both descriptive and inferential statistics. Examples of descriptive tests are the calculation of percentages of different ethnic groups among survey respondents, and the calculation of mean, median and SD for variables such as Asthma Control Test (ACT), Patient Health Questionnaire depression scale (PHQ-8), Quality of Life (EQ-5D-5L) and Generalised Anxiety Disorder (GAD-7) scores, age, etc. The exact nature of a given analysis will depend on the outcome variable, that is, continuous, binary, ordinal, categorical etc., allowing for structure in the data. For example, binary outcomes (eg, uptake of digital intervention (yes, no)) will be analysed by means of a logistic model regressing on key covariates and a term for GP practice to acknowledge possible variation at this level. For continuous outcomes (eg, ACT, PHQ-8, GAD-7 and EQ-5D-5L scores), an analogous linear regression model will be used.

Findings will assist in building the profile of patients interested in digital social interventions versus the profile of patients unlikely to be interested, and how level of interest relates to level of asthma control.

The self-reported data at baseline and after the intervention will be analysed using descriptive and inferential statistics (ie, regression models, in a manner similar to analysis of key study outcomes as described above), and will also be linked with patient data from clinical records over the follow-up period and 3 months prior to recruitment into the study. As is the case for analysis of key outcomes, it is emphasised that the sample size is not predicated on a hypothesis or to estimate a parameter at a specific level of precision, rather the objective is to demonstrate that data can be collected to estimate key parameters (which can then be estimated with an appropriate degree of precision in the main trial). We will present descriptive measures of data completeness (collected during intervention visit versus self-reported online at follow-up), confirm our ability to link routine primary and secondary care data and to cost healthcare use recorded in routine or study databases. We will present descriptive data on key outcomes: number of asthma exacerbations over the last 3 months; primary and secondary care health service utilisation and associated NHS costs over the last 3 months; OHC engagement metrics (ie, amount of engagement, communities joined, number of logins and likes and time spent on pages), public posts and metadata (ie, time of post, thread and user details); and time to deliver the study intervention. These descriptive analyses will be exploratory in nature and focus on the feasibility of linking the different data sets and testing our ability to analyse the outcomes of online peer support for the purpose of statistical and health economic analysis.

Qualitative analyses

Audio-recordings from the exit interviews will be transcribed verbatim and analysed thematically. The six stages of reflexive thematic analysis by Braun and Clarke will be used.[35] Both inductive and deductive approaches will be employed in thematic analysis coding.[36] Coding schemes as well as themes and subthemes will be informed by social support theory (as framed by Dennis)[30] and will aim to synthesise and interpret views on the recruitment strategy, feasibility, acceptability and satisfaction with the

intervention as well as on the perceived impact of taking part in a research study on OHC use (passive or active) and on barriers to OHC engagement. Special focus will be paid on witnessing 'direct' (ie, directly influencing health outcomes), 'buffering' (ie, buffering negative impact of stressors on health) and 'mediating effect' (ie, indirectly influencing health through emotions, cognitions and behaviours) in interview data, which are the main 'effect models' (ie, mechanisms leading to positive outcomes) underlying peer support interventions according to Dennis's framework.

OHC activity data analysis

Data relating to the activity in the ALUK OHC will be analysed through qualitative (eg, thematic and content analysis) and quantitative techniques (eg, descriptive and inferential statistics) as well as network science methods (eg, network measures and visualisations). Analyses of these data will aim to generate meaningful themes (eg, themes related to self-management support and patterns of online communication leading to improved self-management behaviours); quantify online peer support received versus that offered within the OHC environment; develop visual maps of the network between participants and of information diffusion within that network; and understand correlations between engagement with other peers and outcomes. For thematic analysis, the method of Braun and Clarke[35] will be used and both inductive and deductive approaches to coding[36] will be pursued. Should certain themes relating to self-management behaviours be identified, the frequency of these concepts will be further explored/quantified in the whole data set via conceptual forms of content analysis.[37] Theoretical mediators of the intervention effect (ie, 'direct', 'buffering' and 'mediating effect model' mechanisms) will also be measured. OHC activity data will be linked to health-related data and Dennis's conceptual model will be employed to link improvements in patient outcomes to'effect model' mechanisms.[30] As for network analysis, dynamic networks will be constructed and visualised to show the evolution of users' activities in the OHC. Basic network properties will be quantified with centrality measures. Ego-centred networks will also be constructed, and Burt's measures of structural holes and brokerage[38] will be applied to provide in-depth understanding of users' social capital. Furthermore, regression analyses will be conducted to unveil the correlation between network properties and users' health-related outcomes.

Progression criteria

Progression to a pilot and a main randomised controlled trial will depend on success of the feasibility study, according to the following criteria:

- Ability to recruit three to six general practices for the feasibility study.
- Confirmation of the effectiveness of the recruitment strategy in terms of identifying a sufficient volume of eligible patients.
- Demonstration that the intervention is feasible/acceptable to patients and general practices (eg, at least one GP, nurse/advanced clinical practitioner undertaking the training module in each practice, about 50 patients consenting and receiving the intervention, positive feedback expressed at exit interviews and patients' willingness to share OHC-generated data).
- Confirmation of feasibility of data extraction (eg, ability to collect valid measures from patients and clinical records, data consistency and ability to successfully link study participant data across data sets).

Study timeline

This feasibility study is expected to take approximately 9 months to complete, including recruitment, intervention delivery, follow-up and exit interviews and is expected to run from mid or late 2023 onwards.

Patient and public involvement

Co-design with PPIs has been incorporated into several stages of the development of this study, including through online consultations with the AUKCAR PPI group and public engagement activities.[39] These emphasised the importance of primary care clinicians engendering norms and values in OHC engagement; feelings of loneliness and fear in asthma symptoms and the positive impact of empathy received by peers through OHCs; and the reluctance of some patients to discuss their condition in an OHC (taken into account when planning recruitment strategies).

PPI input will carry on throughout the delivery of the study, as well as during analysis and dissemination of findings. One of the coauthors (BD) is a member of the AUKCAR PPI group, and one other member of that group will be joining the independent steering committee (ISC) for the study (see below for details). Extensive feedback (via email and during our monthly PPI meetings) has and will continue to be sought from the 100+ members of the AUKCAR PPI group on drafted documents as well as on the intervention protocol and the clinicians' training modules. A dissemination plan (see below) is being codeveloped with the AUKCAR PPI group, and PPI members will contribute to the interpretation of research findings and writing up of research outputs. PPI members may also assist with the delivery of the training for clinicians and the exit interviews. All PPI members involved in the study will be reimbursed in accordance with NHS policies[40] and the INVOLVE guidelines.[41]

Independent steering committee

An ISC has been assembled in accordance with NIHR guidelines. The ISC consists of a chair (Professor Henry Potts), two members with expertise in ethics and qualitative methodologies in primary care research, respectively (Dr Kirstie Whitaker and Professor Sarah Tonkin-Crine), a senior statistician (Dr Taeko Becque) and one patient with asthma (Ms Amanda Roberts). The ISC will meet annually, with additional 'ad hoc' meetings if necessary and will provide overall expert external supervision.

ETHICS AND DISSEMINATION

Ethical approval and issues

The study has been reviewed by the NHS North East—Newcastle and North Tyneside 1 Research Ethics Committee (reference: 22/NE/0182) and the Health Research Authority (Integrated Research Application System Project ID: 314672) and has been given a favourable opinion for conduct.

The ethical and information governance issues associated with promoting online peer support in primary care are thoroughly discussed elsewhere.[42] Potential risks and discomforts associated with participation in this study are minimal. Participation will be voluntary. Participants will be free to withdraw at any time, without prejudice.

Receipt of the intervention will not affect the normal treatment or care that the patient would have otherwise received. The ALUK OHC is well-established and moderated, and any advice offered within this platform is genuine. Our previous research revealed that patients in the ALUK OHC have reassuring awareness of the limits of their expertise/advice, allotting medical management tasks to healthcare professionals.[43]

Consent

All participants will have the opportunity to ask questions at any stage of the study (by emailing/phoning members of the research team). Completion of the survey will be taken as implied consent for use of the data provided. Written consent will be collected by the clinician before intervention delivery and after verifying the patient's capacity to consent. The consent form (see online supplemental material 3) will cover the intervention delivery, the collection of health-related measures and linkage with data from clinical records and the analysis of activity in the ALUK OHC, including the disclosure of their email address to enable tagging of their OHC activity. The clinicians will add a code on the patient's clinical record indicating their participation in the study.

Written consent will also be sought for the exit interviews, with interviewers asking participants to sign a consent form (see online supplemental material 4).

Adverse events

The intervention in this study does not contain any physical and/or intrusive procedures, hence is unlikely to cause adverse events. Due to the nature and design of this study (involving a one-off, low-risk intervention with no planned subsequent interactions between participants and research team), regular safety reporting of adverse events will not occur. However, the wider primary care team in the recruitment sites will still report to the research team any adverse events they note (the presence of a relevant code in online clinical records will clearly indicate participation in our study). In the unlikely event that any adverse events come to our attention, the study chief investigator (ADS) will act as the medical assessor on behalf on the sponsor (QMUL), will review all events reported and ensure that safety monitoring and reporting is conducted in accordance with the sponsor's requirements.

Dissemination plan

Dissemination activities will run throughout the project with results being disseminated to key stakeholders. AUKCAR, ALUK and our industry partner HealthUnlocked will advise on and contribute to the dissemination of the project findings (employing their digital and social media platforms). We will also seek advice and help from the QMUL Press Office and the NIHR Communication Team.

Dissemination methods will include publications in peer-reviewed journals; presentations at academic and primary care conferences; reports and briefings (eg, for policymakers); newsletters to participating practices and patients; webinars, traditional media and social media; workshops and coapplicants' professional networks and links with guideline groups.

As soon as research outputs are submitted for publication in peer-reviewed journals, executive (lay) summaries will also be prepared. These summaries will be disclosed to the general practices used as recruitment sites, which will be asked to disseminate findings through their own communication channels. Participants will not be individually identifiable from any research outputs.

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