

## **Study Protocol**

***EEABS: Evaluation of the impact of Essex Coronavirus Action Support (ECAS) upon Attitudes, Behaviour and public health Systems during the COVID-19 pandemic***

## ***Full title of the study***

***EEABS: Evaluation of the impact of Essex Coronavirus Action Support (ECAS) upon Attitudes, Behaviour and public health Systems during the COVID-19 pandemic***

## ***Protocol version number and date***

Version 3.0, 22<sup>nd</sup> July 2021

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### FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
NIHR	This study forms part of a grant of £1.5 million allocated to PHIRST London to undertake intervention evaluation.

### STUDY SUMMARY

Study Title	<b>EEABS: Evaluation of the impact of Essex Coronavirus Action Support (ECAS) upon Attitudes, Behaviour and public health Systems during the COVID-19 pandemic</b>
Study Design	Mixed methods evaluation
Study Participants	Work Package 1 Main analysis (new data) n = 450 Work Package 2 Interviews (new data) n = 17-22
Planned Study Period	March 2021 - January 2022

Research Question/Aim(s)	<p>The project aims to evaluate ECAS via the following questions:</p> <ul style="list-style-type: none"> <li>• How effective is a digital community development approach during a pandemic?</li> <li>• Was the ECAS digital community development approach successful in achieving improved health literacy, protective health actions and community connectedness and mutual aid?</li> <li>• Was the ECAS digital community development approach successful in achieving whole system change for the public health function?</li> <li>• What factors were important in contributing to the outcomes?</li> </ul>
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## ROLE OF STUDY SPONSOR AND FUNDER

*PHIRST London* is one of 4 UK Public Health Intervention Responsive Studies Centres funded by NIHR. It is hosted by London South Bank University (LSBU).

## ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

### *PHIRST London Centre Executive Committee (CEC)*

The CEC sits within the sponsor organisation, LSBU. It has management and governance responsibility for PHIRST London and is made up of the Centre Co-Investigators, senior academic staff at LSBU and a lay representative from LSBU's People's Academy.

### *PHIRST London Advisory Group*

The Advisory Group provides overall supervision for the Centre and each of its projects including EEABS on behalf of the Project Sponsor and Project Funder and ensures that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. Membership has been approved by NIHR.

### *Project Stakeholder Group*

A local stakeholder group is in place to ensure liaison between the research team, the local project leads and PPIE representatives. The group is represented by Essex County Council, ECAS Community and PPIE Admins.

**KEY WORDS: COVID-19, online intervention, health literacy, infection prevention, health promotion, digital community development**

## **Background**

### **Protocol Design Process**

This protocol has been developed in collaboration with local stakeholders from Essex through a series of workshops designed to assess the evaluability of the intervention and generate an agreed set of evaluation questions and design. Our approach to assessing evaluability is informed by the five questions identified by Ogilvie et al. (2011) and the stages within the Evaluability Assessment framework developed by What Works Scotland (Craig & Campbell, 2015): a structured engagement with stakeholders to clarify evaluation goals; agreement of an intervention logic model or theory of change; a review of existing research literature and data sources; and making design recommendations. These stages were incorporated within an introductory meeting with the Essex team followed by three structured online workshops facilitated by LSBU. Each workshop lasted three hours and was attended by: the PHIRST London research team, key stakeholders from the local intervention and PPIE representation. During these facilitated workshops we worked towards a shared understanding of:

- the aims and processes of the intervention;
- the logic model and theory of change underpinning the intervention (see Figure 1);
- the existing evidence and gaps in knowledge;
- an evaluation question that is feasible and useful to both the local intervention and the wider public health community;
- an appropriate evaluation design plan.

Communication continued with the Essex team after the formal workshop process to allow joint decision making around specific aspects of protocol design.

### **Social media within health promotion**

Social media has changed both the speed and nature of society's communication (Livingstone, 2015). Networking sites can provide a dynamic and cost-effective way of achieving wide reach, including scientific and practitioner audiences as well as the public. This may help ameliorate barriers to the dissemination of public health messages (Lister et al., 2015).

Social media platforms are increasingly being used for the delivery of health promotion, but public health social media interventions have differed in their health aims (Simeon et al., 2020), examples of such aims include promoting HIV testing, mental health, physical activity, diet and nutrition, vaccination, smoking cessation and reducing alcohol consumption.

Researchers and practitioners do need to understand how to best utilise social media (Gatewood, Monks, Singletary, Vidrascu & Moore 2020). This includes how to engage with audiences, effective strategies and best practice. The literature calls for better quality social media interventions, with comprehensive descriptions, longer follow-up and use of contemporary platforms (Hsu, Rouf & Allman-Farinelli, 2018; Giustini, Ali, Fraser & Kamel Boulos, 2018).

## Understanding how outcomes are achieved

The likelihood of achieving desired outcomes may be influenced by the inclusion of Behaviour Change Techniques and a need for features to increase self-efficacy has been identified (French, Olander, Chisholm & Mc Sharry, 2014). More information on the effects of specific features is needed to guide designs of digital behavioural change interventions (Elaheebocus, Weal, Morrison & Yardley, 2018).

Public health campaigns on social media have shown a tendency to focus on dissemination rather than engaging and interacting with users yet there is evidence that social interaction may be key for facilitating health outcomes on social media (Kostygina et al., 2020). For example, longitudinal data has associated smoking cessation with more network ties and direct interactions through social media (Naslund et al., 2017; Meacham et al., 2021). In this way, shared engagement may be more important than volume of engagement.

Interventions may also increase positive attitudes toward help seeking (Burns, Durkin & Nicholas, 2009) and allow accommodation for low health literacy, which in turn may mitigate disadvantages and improve self-care management (Kim & Utz, 2019). Future research has been recommended to investigate the safety and efficacy of peer-to-peer social media interaction for promoting self-care (Elnaggar, Ta Park, Lee, Bender, Siegmund & Park, 2020).

## The intervention of interest

Essex Coronavirus Action Support (ECAS) involves collaboration between Essex County Council (ECC) and The Essex Public Health Team as well as local Facebook groups. It focuses on the provision of three services: *preventing* the spread of infection, *informing* Essex residents of guidance and *assisting* residents who may be vulnerable. The ECAS Facebook page which was created on 14<sup>th</sup> March 2020 ('Essex Coronavirus Action', 2020) is now followed by 55,339 people (at the time of writing) and is used to distribute information to the community. The related private group created on 15<sup>th</sup> March 2020 has approximately 37,900 members ('Essex Coronavirus Action Support', 2020) and is described as a space for residents of Essex, promoting connection and discussion about issues related to the COVID-19 pandemic.

When membership of the ECAS group is requested, admins ask for a postal code to verify people are Essex residents, members are not actively recruited. Whilst approximately 80% of the demographic is female, men have been reported to be over-represented in discussion ('Mobilizing Essex residents', 2020). There are 18 community admins who oversee the private group, three have a prominent role with ECC paying for their work. Issues around misinformation are dealt with on a case-by-case basis and in rare instances members are banned/ muted if promoting argument.

Growth, recruitment and management have been described as evolving intuitively and some research has been conducted to capture decisions explicitly in terms of team roles, structure and the organisational environment ('Essex County Council', 2021). The co-produced logic model illustrating resources, activities and outcomes as well as their connection (shown in Figure 1) guides the current evaluation of the ECAS intervention.

The proposed evaluation will combine quantitative (Work Package 1, see *Methods* below) and qualitative (Work Package 2) methods to understand the extent to which ECAS achieved its aims to facilitate 'prevent, perform and assist' and also the wider impact it has had on public health system approaches.

## ***Rationale***

### **Promoting behavioural change**

More work is needed to advise which techniques, sometimes referred to as 'active ingredients', should be employed within social media interventions for promoting behavioural change. However, other studies have identified goal setting, social support, information about consequences, comparison, overt endorsement and virtual rewards as some such techniques (Simeon et al., 2020).

### **Context**

Unregulated social media poses health risks, particularly in the context of a pandemic (Höttecke & Allchin, 2020). Studies have indicated that COVID-19 conspiracy beliefs and use of social media as a source of information are positively related whilst COVID-19 conspiracy beliefs and health-protective behaviours are negatively related (Allington, Duffy, Wessely, Dhavan & Rubin, 2020). Congruently, social media platforms and the UK government have introduced a package of measures with the intention of reducing vaccine disinformation (Department for Digital, Culture, Media & Sport, Department of Health and Social Care, The Rt Hon Oliver Dowden CBE MP & The Rt Hon Matt Hancock MP, 2020). This includes platforms working with public health bodies to promote accurate messages.

### **Responding to crisis**

Little is known about how social media platforms have been utilised by public health organisations in infectious disease outbreak scenarios (Merchant & Lurie, 2020). The continual evolution of social media and rapidly changing circumstances of a pandemic present several challenges. There is evidence to suggest that Instagram, more so than Twitter, may be useful to promote meaningful, interactive communication during global health crises (Guidry, Jin, Orr, Messner & Meganck, 2017) when based on communication principles like solution-based messaging, use of visual imagery and acknowledging fears/ concerns.

Whilst this work was Ebola focused, it does mirror strategies proposed to improve public message development in response to COVID-19 (Malecki, Keating & Safdar, 2021) which advocate that communication at the individual, health system and population level should include engaging the audience as partners, communicating with compassion, transparency, honesty and frequent evaluation. Some models have been presented for disaster outreach during the COVID-19 outbreak (Cheng et al., 2020), proposing novel approaches to peer support and crisis intervention using social media applications. There is some evidence indicating usefulness but a need for more formal outcome data.

## ***Project aim***

The current evaluation seeks to build on the existing literature, address the knowledge gaps described above and will uniquely investigate the characteristics of, and techniques employed within, the ECAS Facebook digital community development approach. It will also aim to capture the impact this approach had on wider public health systems. Learning from the evaluation will inform the ongoing delivery of the intervention and planned future initiatives such as the deployment in other regions.

## ***Theoretical framework***

The current study will employ a mixed methods approach to enable a holistic representation of outcomes and allow data triangulation. This is needed as self-reporting and the use of Facebook site activity statistics alone may not provide nuanced and ecologically valid findings and may also introduce a source of bias. It is important, therefore, that both the qualitative and quantitative work packages will incorporate data from salient timepoints across *critical periods* as well as generating new data in order to fully capture cognitive, emotional and actional effects.

Evaluation of any social media intervention needs to account for confounding effects associated with subjective wellbeing and healthy lifestyle (Brailovskaia, Ströse, Schillack & Margraf, 2020) and may need to account for public health awareness and behavioural changes (Al-Dmour, Masa'deh, Salman, Abuhashesh & Al-Dmour, 2020). The current study will explore relationships, influencing factors and underlying processes. The current study will also investigate how discursive devices are employed to achieve social action qualitatively, which is underpinned by a social constructionist approach to knowledge. In addition, social structures facilitating the dissemination of knowledge will be examined quantitatively using graph theory.

Further work is required to confirm effectiveness of social media intervention for promoting health equity (Welch, Petkovic, Pardo Pardo, Rader & Tugwell, 2016; Welch et al., 2018). This is a complex issue as social media interventions should theoretically cross geographical/physical barriers but could inadvertently exacerbate health inequities if the most disadvantaged, and perhaps the most in need, are excluded due to lack of access to technology or the internet. Inclusion of a comparator sample in the current evaluation's quantitative workstream will enable demographic comparison in relation to such issues.

One output of the sandpit workshop series was a logic model describing the inputs into the intervention, the activities alongside short, interim and long-term outcomes (see Figure 1). This logic model guides the design of both work packages. The project also draws on understandings of public health from social identification / connection perspectives (e.g., Haslam, Jetten, Cruwys, Dingle & Haslam, 2018), models of health literacy (e.g., Sykes, Wills, Frings, Church & Wood, 2020) and existing conceptualisations of the assumed mechanisms of social media interventions for behaviour change (Welch et al., 2018).



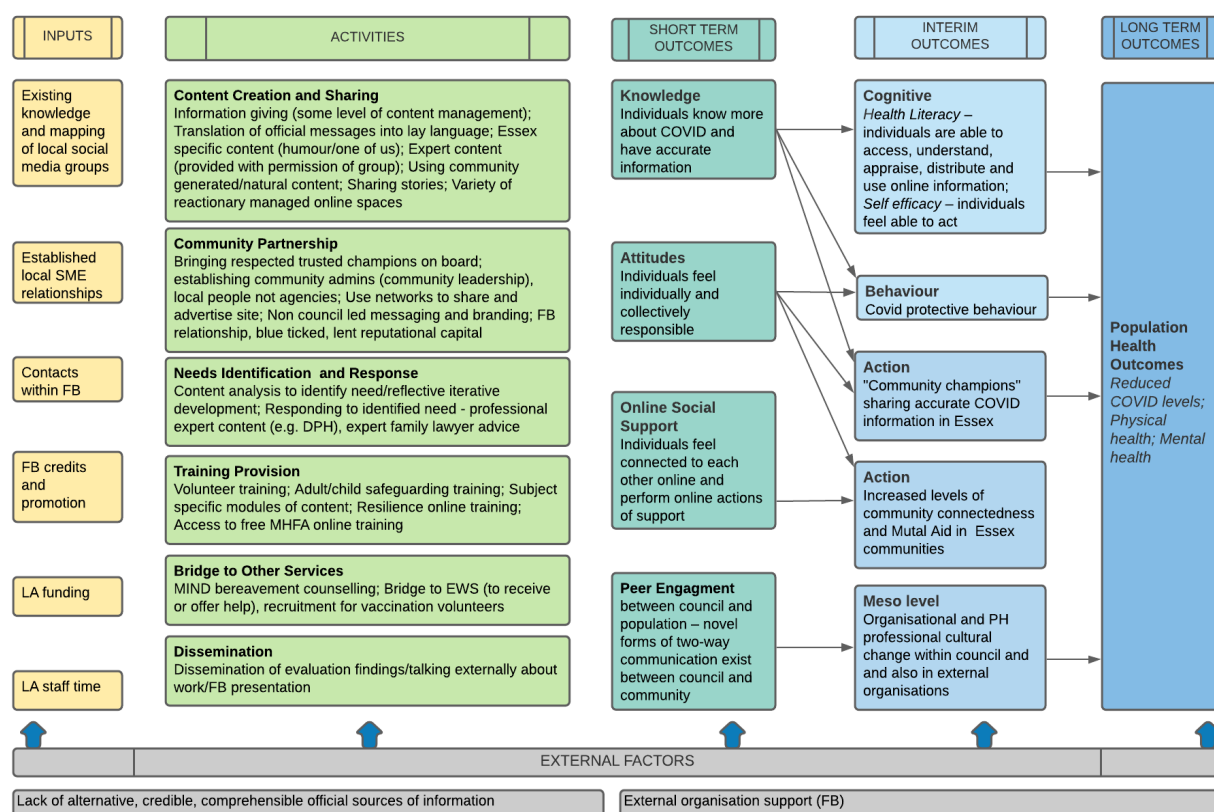


Figure 1: Logic model for the ECAS intervention

## Research question

The project aims to evaluate ECAS via the following questions:

- How effective is a digital community development approach during a pandemic?
- Was the ECAS digital community development approach successful in achieving improved health literacy, protective health actions and community connectedness and mutual aid?
- Was the ECAS digital community development approach successful in achieving whole system change for the public health function?
- What factors were important in contributing to the outcomes?

## Study design, methods and analyses

### Work Package 1: Quantitative work package

This work package will undertake a primary analysis of new data gathered by the research team, and a social network analysis drawing on existing data from the Facebook group. The quantitative strand of the project will test how engagement (or not) with the ECAS intervention impact the interim-term outcomes identified in the logic model.

## Primary analyses of new data

**Effects of ECAS and underlying processes:** For those that have joined ECAS, we will test how engagement with the ECAS Facebook page and group relates to (i) a sense of social connection and (ii) how both engagement and the sense of social connection relate to the interim outcomes of increased health literacy, covid protective behaviour and community champion activity (see Figure 2). A further analysis will compare levels of each of these factors amongst those who did engage with the intervention versus a comparator group who did not and across socio-demographic groups if the data allows (i.e., using moderation analyses). Amongst both samples, we will also measure current levels of mental health and test relationships between these and each factor. These analyses will provide a quantitative evaluation of the extent to which the intervention met its aim to ‘inform’, ‘prevent’ and ‘assist’. Additionally, for those who engage in it, it will also identify which interim outcomes were most impacted and the extent to which this effect was mediated by social connection.

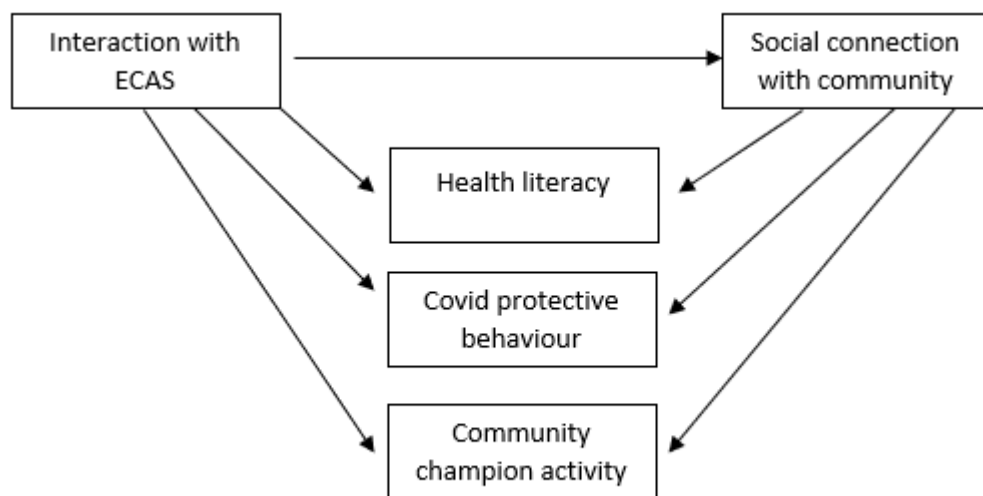


Figure 2: Primary conceptual model to be tested.

Given the nature of the study, much of these data will be retrospective (i.e., people’s recollection of their behaviours). In these instances, we will ask participants to recall how they felt during what our preparatory work with stakeholders (stakeholder workshops and also a PPIE workshop), identified as a *critical phase* of the intervention’s deployment. The critical phase selected for the quantitative analysis of new data is the the first two weeks following the lifting of the first lockdown.

Table 1 (see below) indicates broad operationalisations of each of the factors, the source of data (and whether it is current or retrospective) and possible measurement instruments.

*Table 1: Indicative primary outcome measures<sup>1</sup>*

<b>Factor</b>	<b>Operationalisation(s)</b>	<b>Source of data</b>	<b>Indicative instrument</b>
Interaction with ECAS	Did / did not engage with site  Intensity of engagement (users only)	Facebook data or self-report	Study generated scale/metrics
Social connection	Sense of social connection with others  Collective responsibility	Self-report (current)  Self-report (critical phase)	Validated scale (Lee, Draper & Lee, 2001)
Health literacy	Level of perceived digital health literacy	Self-report (current)	Use of two subscales: information searching and evaluating reliability from validated scale (Van der Vaart & Drossaert, 2017)
COVID protective behaviours	Engage in behaviours which are likely to reduce infection risk to self and others	Self-report (critical phase)	Items from Freeman et al. (2020)
Community champion activity	Helped others practically in real world  Signposted to online reliable information  Corrected misinformation online	Self-report (critical phase)	Study generated scale
Mental health	Level of anxiety  Satisfaction with life  COVID specific anxiety syndrome	Self-report (critical phase)	GAD-7 (7 items)  PHQ-9 (9 items)  SWLS (~5 items)  Nikčević & Spada (2020)
	Level of anxiety	Self-report (current state)	GAD-7 (7 items)

<sup>1</sup> Use of tools is subject to securing permissions, where required, from authors.

The relationships highlighted in Figure 2 will be analysed using the Hayes PROCESS macro tool (Hayes, 2018), focusing on one effect and mediation per model (see power analysis below for a rationale).

This aspect of the research will also take additional *secondary outcome measures* from those who engaged with ECAS including *sense of ownership of the site* (self, community, local authority), *understandings of information provenance*, *confidence in information*, *frequency of referrals made to the site* and *reliance upon site*. This will allow exploratory testing of how these factors relate to the efficacy of the intervention. These will need to be short measures (i.e., single item scales) given the length of the primary outcome measures and subsequent possible impact upon participant attrition.

### **Analysis of existing data**

**Social network analysis:** We will explore the feasibility of using social network analysis (SNA) to see the extent to which influence (categorised as interactions) in the network is central (via admins out to members) or distributed (member to members, including core member and peripheral members) over a given time period (see *Sampling*, below). Data will be analysed using the SNA package on R.

**Sentiment analysis:** Sentiment analysis, through use of Linguistic Inquiry and Word Count (LIWC) software, will computationally assess affective change for individuals using the ECAS Facebook group. The corpus will be consistent with that selected for psychological discourse analysis within Work Package 2 (see below), for consistency, to enable triangulation and heighten human monitoring of content. Our evaluation will test the extent to which negative affect in member discussion around protective health action topics decreased over time between the critical periods, and also the extent to which positive affect in response to ECAS dissemination of public health messages increases.

**Health equity:** To evaluate how widely and amongst how diverse a population the intervention was accessed we will compare the demographic of people using ECAS against the demographic profile of Essex. This analysis will include data from the core provision (Facebook) but also other platforms where ECAS presented information (i.e., Instagram, Twitter).

### **Work Package 2: Qualitative work package**

The qualitative strand of the project will examine which factors were important in contributing to the outcomes of:

- Achieving improved health literacy;
- Encouraging protective health actions;
- Enhancing community connectedness and mutual aid.

It will also explore how the digital community development approach sought to achieve whole system change for the public health function.

The overall approach is *digital ethnography*, also known as online or cyber ethnography, which seeks to study online communities and their cultures (Caliandro, 2014). It adapts the traditional methods of participant observation, interviews, documentary analysis and surveys

to studying online communities. Digital ethnography will be used to analyse online interactions between people connected through technology.

The qualitative work stream will have two components:

**Qualitative component 1: Participant observation of Facebook interactions analysed using discourse analysis:**

Facebook interactions in the form of posts and comments will be analysed using psychological discourse analysis (Goodman, 2017) to analyse how communication is used to mobilise social action, e.g., framing authority differently to engage members to collective action. The analysis will focus on what has been achieved through conversations rather than what the members are thinking.

Previous research about building online communities has identified discursive strategies such as affective responses (use of humour, expressing emotions, self-disclosure), interactive responses (continuing a thread, quoting others, asking questions, expressing agreement) and cohesive responses (addressing the group using 'we' and 'us', using names; Rourke, Anderson, Garrison & Archer, 1999).

The analysis will focus upon:

- How communication seeks to mobilise social action and promote members to engage in protective health actions;
- Examine the extent to which influence (categorised as interactions) in the network is central (via admins out to members) or distributed (member to members, including core member and peripheral members).

The Facebook discussions during the chosen time periods will be anonymised, exported as data files and imported into NVivo qualitative data analysis software. There will be three researchers who will be responsible for data analysis and this will commence with separate analysis of initial data and meetings to compare analysis and develop a shared coding framework.

The sub-questions that will be the focus are:

1. What discursive devices were used to:
  - a. Build and maintain an online community?
  - b. Encourage members to engage in protective health actions?
  - c. Contribute to community connectedness and mutual aid?

Based upon PPIE feedback, the analysis will include what role members adopt, e.g., as info gatherer, info sharer, for support and discussion. The analysis will be informed by a typology of roles identified in the literature, e.g., 1) sporadics; 2) lurkers; 3) socialisers; 4) debaters; 5) actives (Brandtzaeg & Heim, 2011).

2. How do these forms of discursive practice contribute towards achieving whole system change for the public health function?

### **Qualitative component 2: semi-structured interviews with:**

- a. Key Essex County Council staff who designed the intervention
- b. Essex Public Health Team
- c. Facebook admins

Interviews will focus on understanding how the approach seeks to achieve its goals through social media and how these online communities can be used to mobilise social action and mutual aid. Interviews will be transcribed and analysed using framework analysis (Gale, Heath, Cameron, Rashid & Redwood, 2013).

### **Data analysis**

Data will be assessed in the first instance to establish completeness or otherwise. Missing data will be managed with appropriate statistical methods such as mean or multiple imputation, or complete case analyses, depending on the degree of data missing.

A cost consequence analysis will be performed in the first instance with any changes in the outcome measures data and resource use data described separately. This disaggregated approach to presenting the data will assist in helping to fully understand patterns of resource use and benefits separate to costs in the first instance.

Thereafter resources will be converted to establish if there is any potential cost savings or cost effectiveness achieved and a cost per unit of change based on all of the evaluation main measures of change will be conducted.

Measures of variability such as standard deviation and inter-quartile ranges will be used to capture outliers in terms of costs and allow uncertainties in cost to be better understood given a tendency for cost data to be skewed.

Sensitivity analyses with altered assumptions around costs and effects to ascertain uncertainty and provide wider information and parameters on best case, worst case scenarios will be conducted.

## ***Samples and recruitment***

### **Sampling**

**Work Package 1:** We will aim to recruit a sample of  $n = 225$  people who have signed up to the ECAS Facebook page and group. We will also recruit a comparative, equally sized sample of Facebook users who did not sign up to the page nor recall being exposed to it. These will be either a comparative demographic profile, or we will weight responses to match our samples. Recruitment will be conducted via Facebook. The total target sample size will be  $n = 450$ . See *Recruitment*, below, for details on how these samples will be secured.

### **Inclusion criteria:**

- 18+ years of age

- Facebook user
- Enrolled in ECAS page and group on Facebook (ECAS condition only)
- Works or lived in Essex during first lockdown period

#### Exclusion criteria:

- Enrolled in ECAS page and group on Facebook (comparator condition only)
- Unable to give informed consent

**Social network analysis:** Data will be collected from the ECAS group page drawing on posts made (i) during the first two weeks of the first lockdown and (ii) the first two weeks following the lifting of the first lockdown. In each period, the highest day traffic will be selected, then the lowest (non-contiguous) day and then the non-contiguous day closest to the mean. We will manually sample and code 800 contiguous interactions per day, three days per phase (total n = 2400 interactions).

#### Size of sample

**Primary analysis sample:** Our within condition sample of n = 225 allows detection of single mediation effects at power = 0.81 assuming medium (Pearson  $r = .30$ ) relationships between variables (calculated using 'pwr2ppl' R package 'med' function). In the absence of suitable pilot data, these levels of relationship have been selected as they represent effects which are likely, and are in line with relationships between social identity and efficacy and efficacy and behaviour observed in other studies (i.e., Frings, Wood & Albery, in press). Relationships smaller than that powered for are also likely to be of less practical significance. A sample sufficient to power multiple mediation models is beyond the scope of the current study.

**Social network analysis:** This sample size indicated above balances a manageable amount of data inputting and sufficient data to generate meaningful insight. Focusing on high and low traffic days gives a representation of time the group is seeking and receiving information from the centre of the network and times when they are engaged in more general interaction.

**Work Package 2:** Sampling techniques for each aspect are detailed in Table 2.

*Table 2: Recruitment methods for Work Package 2*

Research method	Sample and sampling technique
Discourse analysis of online Facebook conversations	<p>Facebook posts, comments and discussions will be analysed in samples of 1-2 weeks at key points:</p> <ul style="list-style-type: none"> <li>• The initial lockdown and set up phase (March-April 2020)</li> <li>• Interim period between the first and second lockdowns (July/August 2020)</li> <li>• The second lockdown (Oct-Nov 2020)</li> </ul>

	<ul style="list-style-type: none"> <li>• Interim period between the second and third lockdowns (July/August 2020)</li> <li>• The third lockdown (Jan 2021)</li> </ul> <p>This will enable the analysis of each lockdown as well as comparison with lower activity periods between these active periods</p>
Qualitative semi-structured interviews	<p>A total population sampling strategy will be used to purposively sample all staff within Essex Public Health and the Facebook admin team:</p> <p>Key Essex County Council staff who designed the intervention (n = 5-6)</p> <p>Facebook admins (n = 6-8)</p> <p>Wider staff within the Essex Public Health team (n = 6-8)</p> <p>Total sample = 17-22 participants</p>

### ***Sampling technique***

**Work Package 1:** The study will draw upon a convenience sample of individuals recruited from the ECAS platform, and the comparative sample from Facebook in line with the inclusion and exclusion criteria above. Our health equity analysis will help us to evaluate the extent to which the chief samplers are representative of the ECAS population and the wider population of Essex. Should the sample be non-representative, we will explore the need to weight responses accordingly.

Social network analysis: Purposive sampling will be undertaken to capture representative patterns of activity - please see *Sampling* (above).

**Work Package 2:** See Table 2 for sampling techniques.

### **Recruitment**

**Work Package 1:** Where new data are collected, we will recruit directly for the ECAS group via a series of posts promoting the study. For the comparator sample, a range of community Facebook groups will be contacted (with permissions to post sought from moderators where the group's usage terms require this), supported by paid posts promoting the study to the target population. We will incentivise both groups via use of vouchers.

For the *social network analysis*: please see *Sampling* (above).

**Work Package 2: *Qualitative component 2 (semi-structured interviews)*:** Participants for the qualitative semi-structured interviews are all employed by Essex County Council and will be contacted via their work email addresses.

### ***Ethical and regulatory considerations***

#### ***Informed consent***

**Work Package 1: *New data analysis sample*:** A participant information sheet will be provided to all participants giving them full information on the studies' aims, methods and



risks, etc. Contact details will be provided for participants to ask questions prior to taking part. Once participants have read this, they will give written consent to participate in the study and for use of the data. This PIS and consent form will undergo automated readability checks and be reviewed by our PPIE panel and also approved by LSBU University Ethics Panel (UEP).

**Work Package 1: *Social network analysis*:** No consent will be sought from group members, however all data will be anonymised at the point of encoding into the dataset. Sensitivities around data use have and will also be discussed with the PPIE group. Permission to use data in this way will also be sought from the group's administrator and also LSBU UEP.

**Work Package 2: *Qualitative semi-structured interviews*:** A participant information sheet will be provided to all participants giving them full information on the studies' aims, methods and risks, etc. Contact details will be provided for participants to ask questions prior to taking part. Once participants have read this, they will give written consent to participate in the study and for use of the data. This PIS and consent form will undergo automated readability checks and be reviewed by our PPIE panel and also approved by LSBU UEP.

### **Ethical oversight**

The research will receive ethical oversight from LSBU UEP and also Essex County Council as required. This oversight will include the study protocol and all participant facing documentation, and a favourable opinion will be secured before any data collection takes place. Any adverse events will be reported to the above bodies.

All research will be conducted in line with LSBU ethics panel code of conduct for research involving human participants and the British Psychological Society's ethical guidelines. These guidelines include principles of holding participants rights and dignity, anonymity, and freedom to choose to participate or not. Research will also be conducted and reviewed the way which makes it compliant with GDPR (or replacement legislation). Each strand of the research presents a number of particular ethical risks.

### **Work Package 1:**

***New data analysis sample*:** The key ethical risk here is that participants will be asked to recall experiences which occurred over lockdown, which may be upsetting for people. We will mitigate this by fully informing participants of the content of the study in advance.

***Social network analysis*:** The key ethical consideration for this strand of the research is around use of data without participants' explicit consent. Our initial PPIE work has indicated that such a use would be considered reasonable, data will be anonymised at source and only the source, target and length of interaction will be recorded. We will continue to engage with our PPIE group as this work develops. This issue is also more fully explored in ethical considerations for Work Package 2 (see next section).

### **Work Package 2:**

***Qualitative component 1: Participant observation of Facebook interactions analysed using discourse analysis*:** The key ethical consideration here is the detailed analysis of Facebook postings without participants' explicit consent. LSBU code of practice for human research recognises the need for consent in such studies, but also recognises the principle of fair processing and the need for judgement about the extent the use has the potential to cause distress (LSBU Code of Practice for Human Research, 2020, sections 2.1 and 2.2). Feedback

from our PPIE work on this issue confirms that this would be reasonable if the data were anonymised. Feedback also suggested that, although the Facebook group is technically a closed group, it was described as a 'semi-public' space because there are 38,000 members. Furthermore, the only reason that the group is closed is based upon the geographical catchment area. Permission from the site owners/moderators will be obtained.

**Qualitative component 2: semi-structured interviews:** The key ethical risk here is that participants will be asked to recall experiences which occurred over lockdown, which may be upsetting for people. We will mitigate this by fully informing participants of the content of the study in advance and providing support and debriefing if necessary during the interview.

### ***Assessment and management of risk***

*Table 3: Risk register*

<b>Key risk</b>	<b>Likelihood</b>	<b>Impact on participants</b>	<b>Impact on project</b>	<b>Mitigation</b>
COVID19 interferes with staff availability (research team + stakeholders)	Moderate	N/A	Moderate	Depth of team, clear project planning to facilitate handover, lines of alternative communication established, agreement to support the evaluation through a Memorandum of Collaborations between LSBU and ECC
Failure to recruit to quantitative strand	Moderate	N/A	High	Guidance from PPIE in planning stage Leverage market research panel resources
Data not available from partners	Low	N/A	Moderate	Agreement with partners on data, ongoing stakeholder involvement  Agreement in place to support the evaluation through a Memorandum of Collaborations between LSBU and ECC

### ***Amendments***

Significant amendments to the protocol will be discussed in advance with the PHIRST London Central Executive Committee and PH Essex. Should these discussions suggest a need for consultation with the NIHR, this will be co-ordinated by PHIRST London.

### ***Peer review***

This protocol will receive a proportionate review by PHIRST London and the NIHR.

## ***Patient & Public Involvement and Engagement***

The workshops that informed this design were attended by three Essex community members who have been involved in the development and implementation of ECAS. As these members also received a financial recompense from ECC for their involvement, we extended our PPIE strategy to establish a PPIE Advisory Panel made up of ECAS users and Community Admins involved on a voluntary basis. The project aims to have in place a PPIE Advisory Panel of five members in total. Recruitment was undertaken through advertising on the Facebook page and targeted recruitment for Admin. Three panel members have been active so far and further recruitment is ongoing.

The first introductory meeting with the existing PPIE representatives aimed to introduce the project and the research design, following the sandpit workshops. Feedback on the project and acceptability of the research has been positive. The consensus is that the research questions are clear, and users will understand why it is being conducted. Feedback on the research design has been positive. The group are supportive of the methodology and have provided useful insight on assumptions of Facebook page use (frequency and level of engagement of users), recruitment, sampling and ethics in analysing digital content among others.

Future involvement will include A) research tools to ensure (lay) language, flow, accessibility and overall suitability for the target audience, B) critically discuss emerging findings, further analysis that can add to the evidence and related implications of findings. Depending on requirement, this can happen at subsequent stages of the analysis, C) reporting stage for lay summaries and implication of findings, D) dissemination in terms of i) ensuring content is appropriate for both the medium of dissemination and targeted audience, ii) dissemination plan and iii) possible engagement at dissemination stage by way of presenting findings or participation in events, videos etc. This will depend on their availability and willingness to participate.

Future involvement will create opportunities to receive and provide feedback and recognition on their collaboration with the project team, and the impact of their involvement with the project.

## ***Data protection and patient confidentiality***

Where data is collected on third party data collection platforms outside of LSBU (e.g. Qualtrics) data will be anonymised at the point of download, and the third party copy of the data deleted. All data will be kept in an anonymous or pseudo anonymous format and stored on LSBU secure servers. Any key files will be kept on a secure server, encrypted and passwords shared separately from files. Data may be stored indefinitely with participant consent.

Where data is offered to online repositories (see *Dissemination*, below), it will be rendered fully anonymous prior to upload.

When audio files are transcribed, transcripts will be pseudoanonymised. All information which is collected during the course of the research will be kept confidential by using password protected computerised records. All written transcripts will be kept in a secured locked filing cabinet, when not in use. Any information regarding participants that is shared with others (for instance in reports, publications or shared with a supervisor) will also have pseudonyms used, which will prevent the identification of people involved in the study. All data will be secured in a locked filing cabinet for as long as required for the duration of the study and will then be destroyed 18 months after the completion of the project.

## ***Indemnity***

Indemnity will be provided by LSBU for the research activity undertaken by its staff.

## ***Dissemination and output plans***

LSBU will own foreground IP arising from the project, including the final dataset(s) and transcripts. Data will be made available as a 'public good' for secondary analysis (see below). Details of IP ownership and usage rights will be finalised in the collaboration agreement between LSBU and ECAS.

Key research outputs will include:

- 1) Interim report of findings
- 2) A final report for the ECAS team (also lodged on OSF)
- 3) Peer review journal articles (also lodged on OSF)

We will also offer a workshop event in which the study findings are presented to ECAS, and other meetings on an ad-hoc basis as required.

The final dataset(s) will be lodged (in fully anonymous form) on an Open Science Framework site which will also host study documentation, analysis files (syntax, coding frames, etc.) and research outputs associated with the project.

NB The above applies to quantitative work packages only. Qualitative datasets (including interview transcripts and Facebook posts and comments) will not be lodged on an Open Science Framework due to the nature of the data, it may not be possible to fully anonymise these data. In this case, in compliance with the General Data Protection Regulation, data will be kept for 10 years from study completion and will then be destroyed.

## ***Milestones***

<b>Stage</b>	<b>Activity</b>	<b>Completion Date</b>
Inception	Introductory meetings	Jan 2021
	Identification of project team	Feb 2021
	Identification of local stakeholder group	Jan/Feb 2021
	Sandpit workshop 1 - understanding the intervention	25 <sup>th</sup> Feb 2021
	Sandpit workshop 2 - understanding the theory of change	18 <sup>th</sup> March 2021
	Sandpit workshop 3 - agreeing a design	30 <sup>th</sup> March 2021
	Sandpit evaluation survey	March 2021
	Evidence scoping	Feb 2021
	Design and protocol development	March/April 2021
	Ethics application	June 2021
	Research Governance Approval	N/A
	Research Registration	April 2021
	Local PPIE recruitment	Feb-March 2021
	Local collaboration agreement	May 2021

Stage	Activity	Completion Date
Implementation Quantitative Work Package	Primary Analysis Sample - Data collection platform preparation	July 2021
	Primary Analysis Sample - Ad collateral preparation	June 2021
	Primary Analysis Sample - Online marketing admin	Nov 2021
	Primary Analysis Sample - Liaison with recruitment panel inc. admin	TBC
	Primary Analysis Sample - Data collection	Nov 2021
	Primary Analysis Sample - Data screening / preparation	Nov 2021
	Primary Analysis Sample - Analysis	Dec 2021
	Primary Analysis Sample - Data archiving	Jan 2022
	Social Network Analysis – Data harvesting	Aug 2021
	Social Network Analysis - Data screening / fidelity checks / preparation	Aug 2021
	Social Network Analysis - Analysis	Sept 2021
	Social Network Analysis - Data archiving	October 2021
Implementation Qualitative work package	Facebook discourse analysis - Data harvesting	Sept 2021
	Facebook discourse analysis - Initial coding and development of a coding framework	Oct 2021
	Facebook discourse analysis - Main data analysis	Dec 2021
	Qualitative Interviews - Development of interview schedule	May 2021
	Qualitative Interviews - Recruitment of participants	June 2021
	Qualitative Interviews - Data collection	Sept 2021
	Qualitative Interviews - Data analysis	Nov 2021
Project Management and Reporting	Reporting to stakeholder group	Ongoing - TBC
	PPIE meetings	Ongoing - TBC
	Project management meetings	Every six weeks
	Primary Analysis Sample – interim reporting	Dec 2021
	Social Network Analysis – interim reporting	Oct 2020
	Discourse Analysis – interim reporting	Dec 2021
	Qualitative Interviews – interim reporting	Dec 2021
	Final reporting	Mar 2022

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