Protocol | Self-care apps for asthma

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1 Context

1.1 Background

Asthma is one of the most common chronic diseases worldwide, estimated to affect around 300 million individuals (Masoli *et al.*, 2004). Although historically prevalent in developed settings, developing countries are now seeing increases contributing to a global increase in prevalence of 50% per decade (Braman, 2006; Pearce *et al.*, 2000). The United Kingdom has the highest rate of asthma of any country, and prevalence here has increased over recent decades (Anandan *et al.*, 2010; Anderson, 2007; Braman, 2006; Masoli *et al.*, 2004). The high disease burden places significant pressure on the UK health care system adapting to new resource constraints. Consequently, there is a demand for innovative and cost-effective mechanisms of health care delivery, particularly in the context of prevalent and costly chronic diseases like asthma.

These changes have raised interest in self-care programmes that, theoretically, are able to reduce the demand, and increase the capacity, of health care services while improving clinical outcomes for patients (BTS/SIGN, 2011). The rapid evolution of technology experienced over the past few decades provides new opportunities for the design and delivery of self-care initiatives, e.g. improved adherence to inhaled medication regimes in response to an audiovisual reminder integrated into an inhaler (Charles *et al.*, 2007).

Consumer mobile electronic devices (cMEDs, formally defined in 3.1.3.2, below) are of particular interest in the context of self-care. The use of cMEDs, which includes smartphones, is widespread. In June 2010, 73.5% of contract phones sold in the UK were smartphones and 27% of adults now claim to own one (Ofcom, 2010; Ofcom, 2011). The total cost of ownership continues to decline and is competitively placed against other technologies such as laptop and tablet computers (Ofcom, 2010). Consequently, cMED ownership is likely to continue to increase. Smartphones and other cMEDs are increasingly sophisticated computers and uptake means that an increasing number of individuals now possess a device fully capable of a range of functions that might support self-care. Functions can be offered within software extensions that users add to their devices, popularised under the term ‘apps.’ Apps provide a potential platform for the delivery of self-care interventions that are highly customisable, low cost and easily accessible through cMEDs.

The use of interventions delivered via apps accessible through cMEDs is particularly relevant for asthma due to the emphasis on self-care in management of the condition (BTS/SIGN, 2011; GINA, 2010). Conceivably, an app-based intervention might facilitate the monitoring of symptoms and lung function and, when appropriate, alert an individual about deterioration of their condition. A pertinent issue in the management of asthma is poor adherence to prescribed medication (Weinstein, 2005; Lahdensuo, 1999). An app performing an electronic diary function with a reminder feature could help address non-adherence caused by forgetfulness.

1.2 Description of the condition

Asthma is a common, chronic disorder of the airways characterised by paroxysmal and reversible obstruction of the airways in response to an inflammatory trigger. Typical symptoms include wheezing, difficulty breathing, coughing and chest tightness.

A standardised definition of asthma does not exist and, consequently, the diagnosis of the condition is dependent on the individual clinician's assessment of the presenting patient.

The treatment of chronic asthma is centred on a stepwise, pharmacological approach that aims to match disease severity with the complexity of the medication regime prescribed. Inhaled bronchodilators form the main component of this approach and are complemented by anti-inflammatory corticosteroids, leukotriene receptor antagonists and other drug classes in more severe cases of the condition. Treatment aims to control symptoms, prevent acute asthma exacerbations and improve lung function.

All patients with asthma should be reviewed at least annually. The reviews include objective measurement of current symptoms, recording of peak expiratory flow rate and spirometry values, and checking of medication compliance.

1.3 Description of the intervention

Health apps (short for applications) are software designed for cMEDs, such as smartphones and tablets, which aim to promote or support one or more health behaviours.

Although there may be interventions that rely heavily on health apps to achieve their goals, apps are probably best characterised as a delivery mechanism for interventions rather than as an intervention in their own right. This description locates them with other means of intervention delivery, for example paper, email and face-to-face communication. It recognises the broad capability of apps as a medium to communicate information, provide interactive experiences and collect information from patients.

1.4 How the intervention might work

Theories of change provide a means within which to consider how behavioural interventions like self-care programs might work. Recognising that apps act as a delivery mechanism rather than an intervention in their own right, any explanatory account must consider how the delivery properties may act as a modifier within the theory of the intervention.

To illustrate this, we summarise the scope of asthma self-care activities using an Information-Motivation-Behavioural Skills (IMB) model and annotate the points at which the delivery mechanism (i.e. health apps) may act as an enabler. The IMB model links the role of information and motivation with skills acquisition, behaviour and – ultimately – health outcomes (Fisher, Fisher and Harman, 2003).

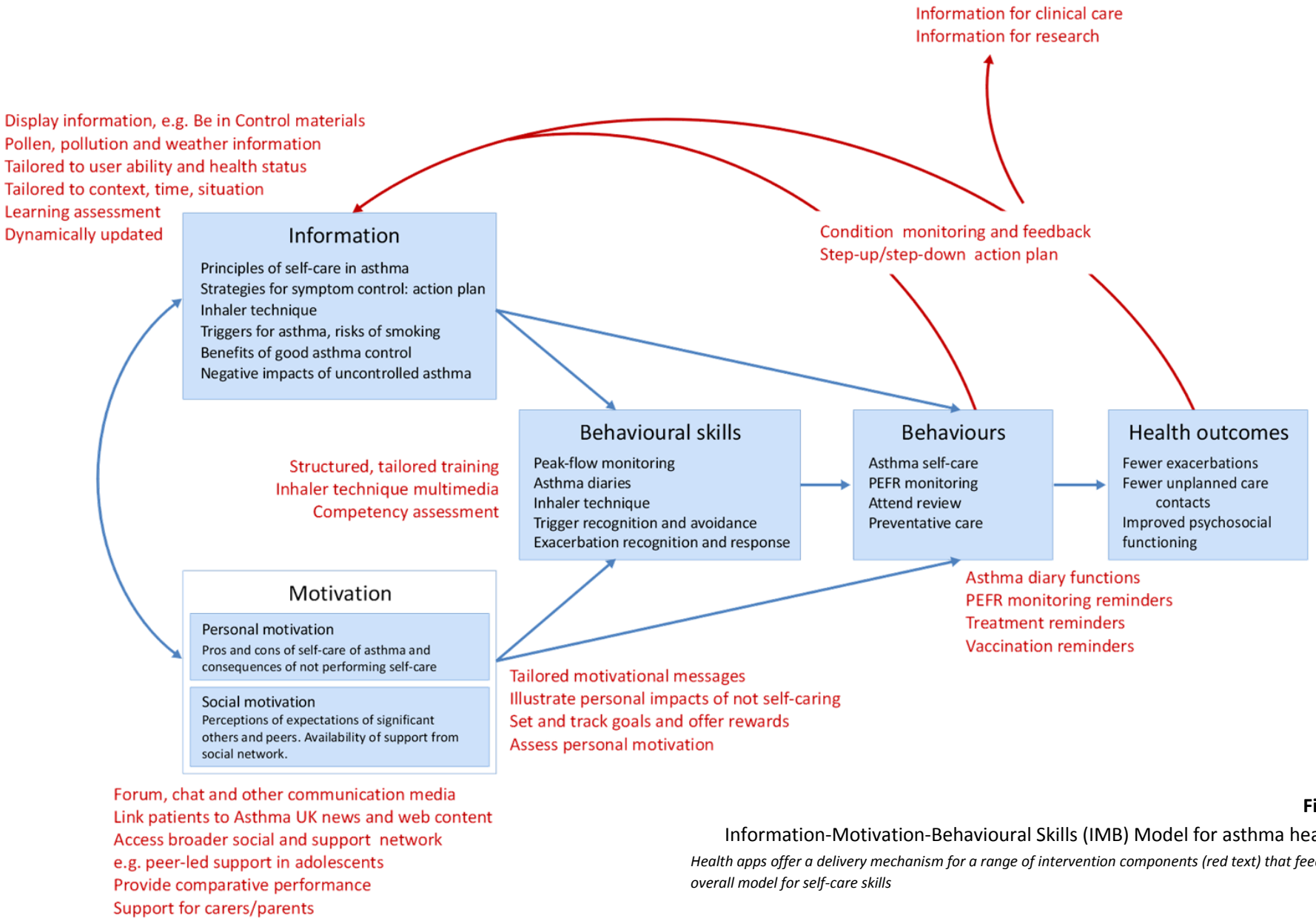

Figure 1.4

Information-Motivation-Behavioural Skills (IMB) Model for asthma health apps

Health apps offer a delivery mechanism for a range of intervention components (red text) that feed into the overall model for self-care skills

1.5 Adverse effects of the intervention

Self-care practices, in general, may present risks to an individual. They are dependent on patients' abilities to correctly manage their condition and, in particular, react appropriately to changes in symptoms. Lacking clinical knowledge or support, management may not be optimal. Moreover, interventions that change the nature of contacts between patients and their healthcare professionals may adversely affect relationships and attitudes.

Poor usability and technical difficulties with a mobile health app, or the hardware on which it operates, may negate the efficacy of a related intervention and affect health outcomes.

Acute asthma exacerbations are a common problem that frequently results in emergency department visits and hospital admissions if severe enough. Patients at high risk of a fatal attack may be difficult to identify and self-care interventions must include appropriate contingencies to handle this type of patient.

1.6 Previous reviews

Existing systematic review literature has not explored the use of information communication technology (ICT) in the management of asthma extensively. Previous reviews have not identified health apps on cMEDs as a distinct intervention category and have focused mainly on randomised controlled trials.

The most recent review concerning the use of ICT in asthma management only included one study which possessed a health app on a cMED as part of the intervention (McLean *et al.*, 2010). More typically, interventions utilised telephone calls or web-based programs under the broad heading of telehealthcare. The review concluded that telehealthcare-based interventions do not confer a significant benefit to asthmatic patients in terms of their quality of life or likelihood of attending the emergency department for an acute asthma exacerbation. However, it does suggest that telehealthcare may result in a reduction in the risk of hospitalisation of asthmatic patients, particularly in those with more severe forms of the condition.

An earlier review explored the clinical effect of computer-augmented asthma care, defined broadly (Sanders and Aronsky, 2006). Interventions were classified into one of four domains: asthma detection or diagnosis, disease monitoring or prevention, patient education, or therapy. The authors highlighted the need for further research in the domain but also point out that few studies demonstrate improvement in clinical outcomes with the use of computer-based interventions.

A systematic review of asthma self-management options did not consider the use of ICT (Powell and Gibson, 2003). Instead, written action plans, regular medical review and education were evaluated. The use of written action plans in the management of asthmatic children has been considered separately (Bhogal, Zemek and Ducharme, 2006).

A larger body of literature has reviewed the effect of education-based interventions on defined outcomes in asthmatic individuals (Boyd *et al.*, 2009; Gibson *et al.*, 2002; Gibson *et al.*, 2003; Tapp, Lasserson and Rowe, 2007; Wolf *et al.*, 2003). A systematic review of patient education programs delivered via interactive computer programs did not provide strong evidence for objective improvement in clinical outcomes (Bussey-Smith and Rossen, 2007).

2 Objectives

2.1 Objectives

To assess the efficacy, suitability and cost of using mobile apps to facilitate the self-care of individuals with asthma

2.2 Intended audience

The review will inform clinicians and policy makers with regards to:

- The clinical effect of incorporating mobile apps into the management of asthma
- The cost-effectiveness of such interventions if they do provide a clinical benefit
- Which patients would benefit most and/or in the most cost-effective manner
- How to design the intervention to increase uptake, compliance and satisfaction
- How to maximise the likelihood that the intervention will achieve a desired outcome
- The weaknesses and limitations of the extant knowledge base on the topic

It is also intended for researchers working in this field.

3 Methods

3.1 Criteria for considering studies for this review

The inclusion criteria for studies are summarised in Table 3.1 and described in detail below.

Populations	Individuals diagnosed with asthma by a clinician in any care setting, and of any demographic background
Interventions	Any self-care intervention involving a health app accessible through a cMED
Comparisons	Intervention versus usual care or any other control intervention
Outcomes	Quality of Life scores; Symptom scores; Lung function measurements; Emergency department visits; Hospitalisation; Time off school or work; Compliance; Satisfaction; Cost; Acceptability
Study Types	Randomized controlled trials; Controlled before and after studies; Interrupted time series studies; Qualitative studies; Economic analyses

Table 3.1
Inclusion criteria summary

3.1.1 Types of studies

We will include studies that have adopted one of the following five types.

- Randomized controlled trials (RCTs, including crossover studies)
- Controlled before and after studies
- Interrupted time series studies
- Qualitative studies that are linked to a primary study adopting one of the above designs
- Economic analyses

Studies of one of these types will be further assessed with regard to the quality of their design. This will determine whether the relevant reported outcomes will be extracted from a particular study (see 3.3.2.1).

Reports of ongoing or unpublished work, in addition to pilot studies, will be included in the review if they are associated with data important to the outcomes of interest (see 3.1.4). In these instances, the authors will be contacted.

3.1.2 Types of participants

We will include studies of individuals with clinician-diagnosed asthma who implement self-care (see 3.1.3.1) practices in any setting.

Asthma cannot be diagnosed according to pre-specified objective, standardised criteria as other conditions may (BTS/SIGN, 2011). Therefore, the inclusion of study participants in this review will be according to the respective diagnostic criteria used in each study.

Individuals without an asthma diagnosis will be included in the review when:

- They form part of a control or comparison group to the asthmatic individual group; or
- They are a parent to, or caregiver for, an asthmatic individual.

Participants will not be excluded on the basis of any other socio-demographic characteristics.

3.1.3 Types of interventions

We will include studies that utilise single or blended (see 3.1.3.3) interventions meeting the defined inclusion and exclusion criteria. These criteria relate to the use of an app accessible via a consumer mobile electronic device (cMED) to facilitate asthma self-care.

Although we will include blended interventions as part of a comprehensive account of the types of intervention that have been tested, we will not include these in all analyses.

The intervention may be used by an individual in any setting.

3.1.3.1 *Asthma self-care*

The WHO (1983) has defined self-care as:

> "[T]he activities individuals, families and communities undertake with the intention of enhancing health, preventing disease, limiting illness and restoring health. These activities are derived from *knowledge and skills* from the pool of both professional and lay experience."

A checklist of asthma self-management skills, from which self-care behaviour may derive, has been described previously (Lahdensuo, 1999). We are interested in interventions that equip individuals with, or help them to sustain and develop, one or more of the 13 skills found on this list:

	Patients should….
I	Accept that asthma is a long term and treatable disease
II	Be able to accurately describe asthma and its treatment
III	Actively participate in the control and management of their asthma
IV	Identify factors that make their asthma worse
V	Be able to describe strategies for avoidance or reduction of exacerbating factors
VI	Recognise the signs and symptoms of worsening asthma
VII	Follow a prescribed written treatment plan
VIII	Use correct technique for taking drugs including inhalants by metered dose inhalers, dry powder inhalers, diskhalers, spacers, or nebulisers
IX	Take appropriate action to prevent and treat symptoms in different situations
X	Use medical resources appropriately for routine and acute care
XI	Monitor symptoms and objective measures of asthma control
XII	Identify barriers to compliance (adherence) to the treatment plan
XIII	Address specific problems that have an impact on their individual condition

Table 3.1.3.1
Self-management skills described by Lahdensuo (1999)

We will **include** any intervention that aims to address one of these skills.

We will include studies that compare different approaches to promotion of a self-care skill and blended interventions that address more than one self-care skill and where not all skills are facilitated by a health app (see 3.1.3.3).

We will include studies in which the intervention may be used by a parent or caregiver to the asthmatic individual of concern.

We will also include qualitative studies that induce the attitudes surrounding the intervention and the aforementioned domains, barriers to compliance and facilitators of intervention delivery.

We will **exclude** interventions that either:

- Lies outside these domains;

  or

- Falls within these domains but where:
  - The participants are not asthmatic individuals or their caregivers;
  - The intervention is targeted only at health or allied professionals rather than patients;
  - The intervention also falls within the NIH definition of complementary or alternative medicine (NIH, 2010) and is not generally considered part of conventional medicine.

3.1.3.2 *Consumer mobile electronic devices (cMEDs)*

We will **include** studies utilising an intervention which satisfies our criteria for a consumer mobile electronic device (cMED) detailed in table 3.1.3.2.

Handheld	A single device with integrated display and input mechanisms (keyboard, touchscreen, touchpad, microphone etc.) that weighs less than 1kg and measures less than 300mm along its largest dimension
Mobile	Operates wholly or substantially without requiring a physical connection to an external power source or other entity
General purpose	Supports computing functions requiring arbitrary software code (see 3.1.3.3)
Instant on	Features are available to the user immediately after turning the device on
Consumer	Available for purchase, by buyers acting within a market, without modification other than to install specific software

Table 3.1.3.2
Defining criteria of a cMED

The criteria aim to identify devices which share similar usability characteristics. A relative degree of homogeneity is required as mHealth intervention adoption is significantly influenced by device characteristics.

The interest in consumer devices specifically emanates from the expectation that the cost and characteristics of bespoke technologies limit their suitability for large scale interventions, such as those that may be required in the context of asthma. We also expect that interventions centred on consumer devices facilitate adoption due to their pre-existing popularity and prevalence.

Devices that require bespoke connecting or ancillary devices are deemed acceptable provided that the consumer device itself is left unaltered.

The criteria incorporate devices with GSM and wireless connectivity (e.g. smartphones) as well as those without (e.g. some personal digital assistants; PDAs). Tablet devices meeting the above criteria will be included.

We will **exclude**:

- Devices using bespoke hardware
- Consumer hardware that requires physical modification for intervention delivery
- Desktop computers, laptops, notebooks and netbooks as these currently offer interaction methods not comparable with cMEDs (e.g. mouse versus touchpad)

Although apps are likely to become available on desktops, laptops and so on in the near future, this does not reflect the current situation.

3.1.3.3 *Health apps*

The term *health app* is used to describe a piece of software for use on a cMED (see 3.1.3.2) that fulfils the following additional criteria. The software must:

- Be *accessible* via a cMED, without necessarily being *installed* (e.g. access via a web browser on a cMED)
- Be an optional add-on to the device in its default form
- Interact with the user via a set of interfaces (e.g. visual user interface)
- Offer one or more functions that are designed to help a user initiate or sustain either:
  - Asthma self-care (see 3.1.3.1); or
  - Health behaviour, for which we use the WHO definition (WHO, 1998)

    'Any activity undertaken by an individual, regardless of actual or perceived health status, for the purpose of promoting, protecting or maintaining health, whether or not such behaviour is objectively effective towards that end.'

    A health behaviour is purposively adopted. Behaviours that are adopted which have consequences for health as side-effects are not included in this definition.

We will **include** interventions that include the use of a health app. The health app can be the sole means by which an intervention is delivered or it may form a smaller part of a composite intervention. We term the former *app-based interventions* and the latter, *blended interventions*.

We will **exclude** interventions that:

- Only use existing software available on a cMED in a new way (e.g. using a calendar as a diary)
- Rely solely on messaging (e.g. SMS and MMS) as the user experience is significantly different from use of software with a defined interface
- Do not offer a mode of interaction but act simply as a transmitter of data (e.g. from patient to clinician) – this is more consistent with telemonitoring than self-care (Paré, Jaana and Sicotte, 2007).

3.1.4 Types of outcomes

It is infeasible and insensible to attempt to define outcomes that directly reflect the morbidity and mortality associated with asthma as these are affected by long-term health behaviours rather than shorter term interventions. However, proxies can be developed which, when considered together as a composite, can indirectly capture these concepts.

Primary outcomes

- Quality of life (QoL) scores measured using a validated standard instrument;
- Symptom scores measured using a validated standard instrument;
- Lung function measurements (PEF, FEV1, FVC);
- Frequency of unplanned health care visits (emergency department, GPs, hospitalizations) due to asthma exacerbation/complications

Secondary outcomes

- Time off school, work or other commitments due to asthma exacerbation/complications;
- Compliance with the intervention;
- Satisfaction with the intervention, assessed using a validated instrument);
- Health economic properties of the intervention;
- Acceptability of the intervention.

We will use these and additional sources to compile details of:

- The scope of asthma self-care activity that health apps can support;
- The characteristics of users who are best positioned to access and use the technology;
- Properties that facilitate intervention adoption, continued use and/or clinical efficacy;
- Barriers to adoption for both consumers and providers which are pragmatic issues (derived from real-world experience) that act either to slow or speed utilisation of the technology;
- Advantages and disadvantages of patient-facing apps compared to current care practices;
- Feasibility of apps as routine interventions for asthma self-care.

Outcomes observed at the time of completion of an intervention will be included in the review, in addition to those measured at subsequent time points as follow-up. Outcomes recorded within 30 days of cessation of the intervention will be regarded as short-term follow-up. Long-term follow-up will be regarded as that continuing at least 6 months after completion of the intervention. Medium-term follow-up will be regarded as that in between 30 days and 6 months.

We will not exclude studies reporting outcomes other than those listed above but they will be retained for purposes of qualitative synthesis and discussion only.

3.2 Search methods for identification of studies

3.2.1 Electronic searches

The following electronic databases will be searched:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- Cochrane Consumers and Communication Review Group Specialised Registrar
- MEDLINE
- EMBASE
- PsycINFO
- CINAHL
- CAB Direct Global Health
- Global Health Library
- Compendex/Inspec/Referex
- IEEEXplore
- ACM Digital Library
- CiteSeer[X]
- ERIC

The search string to be employed within these databases is presented in Appendix 1. Two authors (MR and KH) will perform the search independently and the results compared to ensure accuracy.

Articles published prior to 1980 will be excluded from the search as neither handheld computers, smartphones nor PDAs existed before this date (Terry, 2010; Zeldes, 2010). Studies conducted prior to 2000 will be interpreted with caution as the technologies existing at that time are unlikely to be representative of contemporary technologies.

No language restrictions will be applied to the search.

3.2.2 Searching other resources

The grey literature will be searched using:

- OpenGrey
- Mobile Active, a user-created directory of mobile health solutions
- ProQuest Dissertations

The abovementioned search string will be applied in this context also.

The same date restriction will be applied as before (see 3.2.1).

Articles written in a language other than English will be considered for review only if they possess an English abstract.

We will browse the reference lists of included articles and contact study authors for purposes of clarification or for information on additional relevant published or unpublished studies.

3.3 Data collection and extraction

3.3.1 Selection of studies

EndNote (Thomson Reuters Corporation, New York, USA) will be used to collate the search results from individual databases and subsequently remove duplicate records.

Study selection will follow the process described in section 7.2.3 of the Cochrane Handbook for Systematic Reviews of Interventions (2011) titled 'A typical process for selecting studies.' Two authors (JMB and GV) will independently examine titles and abstracts to remove obviously irrelevant reports. Full text reports will then be retrieved and assessed for compliance with inclusion and exclusion criteria (see 3.1). A third review author (KH) will resolve any disagreement over the eligibility of a particular study between the first two authors. It may be appropriate to correspond with study investigators if a resolution is difficult to reach.

3.3.2 Data extraction and management

The study design will inform the approach to data extraction.

- Data from randomised controlled trials, randomised crossover studies and interrupted time series will be extracted using a systematic and structured approach as detailed in section 3.3.2.1.
- Data from studies employing qualitative methodologies will be analysed thematically (see 3.3.2.2).

The use of qualitative studies in facilitating the interpretation of quantitative outcomes from separate studies has been highlighted previously (Harden and Thomas, 2005).

Classification of a study as a particular design will be informed by the assertions of the authors. Difficulties will be resolved by the reviewers.

Some outcomes will only be extracted from studies of a particular design (see 3.3.2.1).

3.3.2.1 *Structured data extraction*

Two review authors (JMB and GV) will independently extract data from included studies using a structured form (published separately). The characteristics to be extracted from all studies are detailed in table 3.3.2.1.

The data extraction forms completed by each reviewer will be compared and discrepancies followed up with reference to the original article. It may be necessary to contact study authors to obtain missing or incomplete data.

With the exception of cost data, quantitative outcomes will only be extracted from randomised, controlled before and after and interrupted time series designs. Economic data may be derived from these studies or from studies using economic modelling. Satisfaction and acceptability data will be extracted from any study that reports on it in quantitative or semi-quantitative form (a separate extraction will also take place for qualitative studies that explore these outcomes, see 3.3.2.2).

General information	• ID • Source and publication status • Date published • Language • Date of review
Study methods	• Aim of study • Study design claimed by authors • Study design interpreted by reviewers • Method of recruitment • Setting for recruitment • Inclusion and exclusion criteria • Details of control and comparison groups • Incentives for participation
Risk of bias assessment	See 3.3.3
Participants	• Description • Geographic setting for intervention • Place where intervention delivered • Study numbers (at recruitment, eligibility screening, randomisation and follow-up, by intervention group), details of power calculation • For the pooled set of participants (pooled controls and interventions): - Demographic characteristics (mean age; %female; mean BMI; mean income; %secondary education; %BME groups) - Asthma characteristics (severity of asthma; ratio of asthmatic treatment modalities) - Co-morbidities • Assessment of baseline imbalance between groups
Providers	• Details of healthcare worker(s) or systems responsible for supporting the app
Intervention	• Name • Asthma self-management skill • Mode of interaction (no feedback; data entry and visualization without treatment recommendations; data entry with device-generated treatment recommendations; data entry, transmission to a healthcare worker to make treatment recommendations) • Hardware and software technologies used • Key software functions • Software installation process • Main receiver of intervention (patient; carer; healthcare worker) • Mode of data entry (manual; wireless e.g. from a connected monitoring device; etc.) • Training offered to patients and providers • Frequency, duration and intensity of interaction with intervention • Measures of implementation fidelity and programme differentiation • Process and timing for data download from device • Security arrangements • Evidence of consideration of adoption factors in study design • Measures of adherence and protocol deviation
Outcomes	• Time points at which measurements were taken • Outcomes assessed • Assessment methodology; definitions/validation of instruments • Values

Table 3.3.2.1

Characteristics to be extracted from included studies

3.3.2.2 *Qualitative thematic synthesis*

A single author (JMB) will perform a qualitative thematic synthesis (Thomas and Harden, 2008) for all studies that employ a recognised qualitative methodology to explore the attitudes of individuals towards an intervention, such as satisfaction and acceptability. Studies assessing the same outcome will be grouped and their findings coded accordingly. The quality of included studies will be appraised as detailed in section 3.3.3. The results produced by such studies will be presented in their own right but will also provide context and qualification to the complementary results of quantitative studies.

The free text of included studies will be extracted and iteratively coded using NViVo (QSR International Pty Ltd., Doncaster, Australia).

3.3.3 Assessment of quality and risk of bias

Quality has been defined by the GRADE Working Group as, 'the extent to which one can be confident that an estimate of effect or association is close to the quantity of specific interest' (GRADE Working Group, 2004). The corresponding approach to quality assessment is used by health care organisations worldwide including the WHO and NICE. Risk of bias is a factor that must be acknowledged when judging the quality of a study and is specifically addressed by the Cochrane Handbook for Systematic Reviews of Interventions.

The Cochrane Collaboration's tool for assessing the risk of bias in randomized controlled trials will be used as detailed in section 8.5 of the Cochrane Handbook for Systematic Reviews of Interventions (2011). Therefore, the extent of random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias will be assessed. These other sources include the imbalance of outcome measures at baseline, the comparability of intervention and control group characteristics at baseline and protection against contamination as recommended by the Cochrane EPOC group.

Two review authors (JMB and GV) will independently assign each study as either, 'Low', 'High' or 'Unclear' (where there is insufficient information to categorise it otherwise). A third review author(KH) may be included in this process on occasions of disagreement.

In order to address the risk of bias in economic analyses, we will follow the guidance detailed in section 15.5 of the Cochrane Handbook for Systematic Reviews of Interventions (2011).

Quality assessment in the context of qualitative evidence synthesis is contentious. While many tools and frameworks are available to facilitate the appraisal of qualitative research, some argue that the more rigid and uncompromising amongst them are inappropriate (Barbour, 2001; Spencer *et al.*, 2003). Due to the focus on empirical outcomes in this review, we feel that some form of quality appraisal is necessary for qualitative evidence. Therefore, we will adopt the assessment questions posed by Spencer *et al.* (2003).

Reporting bias will be assessed during analysis of outcomes (see 3.4.3).

3.4 Data collection and analysis

3.4.1 Describing the review process

A flow diagram using the PRISMA template will be used to illustrate the process of searching, screening and selecting studies for inclusion in the review.

A table detailing the characteristics of excluded studies, and the reason for their exclusion, will be constructed during the course of the review also.

3.4.2 Narrative synthesis

We will present a narrative synthesis of included studies to address the topics described in table 3.4.2. Where appropriate, information will be segregated by the type of intervention being reported. We will also present a 'Characteristics of included studies' table describing the methods, participants, interventions and outcomes of individual studies.

Study design	• Trial design • Risk of bias • Adherence to protocol (overlaps with 'Compliance' outcome) • Conflict(s) of interest
Participants	• Demographic and socioeconomic characteristics • Psychological characteristics • Other physiological/comorbid characteristics • Self-care status prior to intervention
Interventions	• Setting • Taxonomic components of interventions • Frequency, intensity and durations of interventions • Role of training and other support in interventions • Types of technology used in interventions
Outcomes	• Primary and secondary outcomes • Meta-analysis (if performed, see 3.4.4, below)

Table 3.4.2
Content of narrative synthesis

We will summarise qualitative outcomes in a separate table.

3.4.3 Summary and interpretation of outcomes

The findings of the review pertaining to quantitative outcomes of interventions will be presented in a 'Summary of findings' table.

The GRADE approach described in section 12.2 of the Cochrane Handbook for Systematic Reviews of Interventions (2011) will be used to evaluate the impact of evidence quality on the interpretation of studies' reported outcomes. The approach specifies four levels of quality labelled as 'high', 'moderate', 'low' and 'very low'. The quality rating is partially dependent on a study's underlying methodology but we will upgrade, or downgrade, studies' ratings according to the factors listed in the abovementioned section.

Studies will be assessed for the presence of publication bias if they utilise app-based interventions and are homogeneous across the following three domains.

- *Intervention*
  The intervention content and design encourages the same self-care behaviour (see 3.1.3.1) and is delivered in a similar manner for a comparable duration
- *Quantitative outcome*
  The study reports one of the quantitative outcomes listed in section 3.1.4.
- *Population*
  This domain regards age distribution, gender balance, socioeconomic background, ethnicity, setting of intervention and so forth.

Studies selected on the basis of face evidence for homogeneity (defined by the criteria above) will be evaluated for statistical heterogeneity using the I^2 statistic. If a result is obtained that is greater than 0.5, the assumption of heterogeneity will be considered violated and publication bias will not be assessed (nor meta-analysis performed). Otherwise we will test for publication bias using a funnel plot regression weighted by the inverse of the pooled variance (Macaskill, Walter and Irwig, 2001). A regression slope of zero will be treated as suggestive of no publication bias. We recognise the limitation of current methods to assess publication bias with small numbers of studies (Lau *et al.*, 2006). If fewer than 10 studies are available for analysis then we will not test for publication bias and assume that publication bias could exist.

3.4.4 Meta-analysis

3.4.4.1 *Criteria for performing a meta-analysis*

We will consider performing one or more meta-analyses for any the primary outcome measures if the following conditions are satisfied:

- The overall quality of the available outcome data, assessed using the GRADE approach is high or moderate;
- After assessing the following for each study that reports on the outcome, at least two studies remain:
  - The study is a randomized controlled trial, controlled before-after or interrupted time series design;
  - Study satisfies requirements for face and statistical heterogeneity using the I^2 statistic and criteria described above (3.3.3).

The final decision to perform one or more meta-analyses will be taken at a meeting of all review authors.

3.4.4.2 *Meta-analysis procedure*

We will follow the guidelines for meta-analysis laid out in Chapter 9 'Analysing data and undertaking meta-analyses' of the Cochrane Handbook (2011), using the RevMan Version 5.1 (The Nordic Cochrane Centre, Copenhagen, Denmark) to perform analysis.

Because we will be pooling the results from different interventions linked by a common delivery mechanism, we will use a random-effects model.

3.4.4.3 *Sensitivity analysis*

We will consider sensitivity analysis if:

- One or more studies are dominant in any meta-analysis because of their size (by excluding these studies); or
- One or more studies have results that differ from those observed in other studies (by excluding these studies); or
- One or more studies have quality issues that may affect their interpretation judged using QUADAS and the Cochrane Risk of Bias approach (although the overall assessed risk of bias for the pooled set of studies must be high or moderate, weaker studies may be included).

3.4.4.4 *Meta-analysis presentation*

We will report the meta-analysis procedure using the QUOROM approach (Moher, 1999).

We will summarise data using Forest plots.

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Contributions of authors

This work is based on an existing protocol for a similar review of diabetes authored by KH.

KH conceived the review. TC wrote the first draft of the protocol, KH revised and JC provided comment.

Definitions for cMED and Health App were devised by KH and JC with another author (Michelle van Velthoven).

Declarations of interest

None

Appendix 1

Search strategy

Search Strategy.docx

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