ISRCTN11295269 https://doi.org/10.1186/ISRCTN11295269

Assessing the use of a smartphone application to support adherence to inhaled corticosteroids, i.e. preventer/controller inhalers, in young adults (18-30 years) with asthma

Submission date
22/12/2020

Recruitment status
No longer recruiting

Registration date
18/01/2021

Overall study status
Completed

Last Edited
02/09/2021

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Asthma is a common lung condition that causes occasional breathing problems. Inhaled corticosteroid (ICS) inhalers can help relieve symptoms when they occur (reliever inhalers) and stop symptoms developing (preventer inhalers). Adherence to ICS is a major barrier to achieving asthma control, particularly among young adults. Only 28% of this population adhere to their ICS as prescribed.
Digital Health Technologies (DHTs) such as smartphone apps are almost universally used among young adults and have shown the potential to support adherence to ICS in adolescents and adults. However, it is important that such DHTs are considered usable, acceptable, and feasible by young adults to ensure their successful use in this population. The aim of this study is to assess the usability, acceptability, and feasibility of the 'AsthmaMD' app smartphone app to support adherence to ICS in a population of young adults (aged 18-30) living with asthma.

Who can participate?
Young adults aged 18-30 who are living with asthma, currently prescribed a form of ICS, and own a smartphone.

What does the study involve?
This is an online study involving two brief questionnaires. Participants will be asked to complete a questionnaire about demographics, asthma characteristics, smartphone and app use, and download the 'AsthmaMD' app and use it as they wish for 2 weeks. Participants then complete a follow-up questionnaire about their experience of using the app.

What are the possible benefits and risks of participating?
Taking part in this study may introduce participants to an app which they find beneficial for taking their ICS and managing their asthma, which they can continue to use after the study. This

research will be valuable in informing appropriate support for the wider community of young adults living with asthma.
There are no anticipated disadvantages or risks of taking part in this study. As with all smartphone apps, the maker of the commercial app will have a privacy policy concerning user data. The research team do not control this policy. Participants are encouraged to make themselves familiar with this before agreeing to download the app. None of the individual-level data collected will be shared with anyone outside of NUI Galway, and the research team will not have access to any data recorded by the app.

Where is the study run from?
This study is conducted entirely online. The research team are based at the School of Psychology, NUI Galway (Ireland)

When is the study starting and how long is it expected to run for?
August 2020 to January 2021

Who is funding the study?
Irish Research Council (IRC) (Ireland)

Who is the main contact?
Jane Murphy
j.murphy51@nuigalway.ie

Contact information

Type(s)
Public

Contact name
Ms Jane Murphy

ORCID ID
https://orcid.org/0000-0002-9662-3784

Contact details
School of Psychology
Arts Millennium Building Extension
University Road
Galway
Ireland
H91 TK33
+353 (0)876904980
j.murphy51@nuigalway.ie

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A smartphone application to support adherence to inhaled corticosteroids in young adults (18-30 years) with asthma: a usability, acceptability, and feasibility study

Study objectives
The aim of this study is to: (1) evaluate the usability, acceptability, and feasibility of the 'AsthmaMD' smartphone app to support adherence to Inhaled Corticosteroids (ICS) in a population of young adults (18-30 years) living with asthma, and (2) assess the below Go- and No-Go Progression Criteria for a trial to test the effectiveness of the app.

Go- and No-Go Progression Criteria:
• If all criteria are rated as green, the trial to test the effectiveness of the app can immediately proceed.
• If some criteria are partially met and rated as amber, the trial of the app can proceed once relevant criteria have been reviewed and a plan to make relevant amendments has been agreed by the research team.
• If one criterion is not met and rated as red, the trial can only proceed if (1) no more than 2 criteria are rated red, and (2) a plan to make the required amendments has been agreed by the research team.

1. Feasibility of participant recruitment
Can >74 participants be recruited to take part in the study?
• >74 participants recruited = Go - Proceed with trial (Green)
• >65 participants recruited = Amend - Proceed with changes (Amber)
• <61 participants recruited = Stop – Do not proceed unless changes are possible (Red)

2. Feasibility of participant retention
Can >59 participants be retained until study completion?
• >59 retained = Go - Proceed with trial (Green)
• >50 retained = Amend - Proceed with changes (Amber)
• <40 retained = Stop – Do not proceed unless changes are possible (Red)

3. Usability of ‘AsthmaMD’ app
Will the app receive a mean SUS score >68?
• SUS >68 = Go - Proceed with trial (Green)
• SUS >63 = Amend - Proceed with changes (Amber)
• SUS <52 = Stop – Do not proceed unless changes are possible (Red)
And
Interpretation of qualitative data from open-ended questions relating to usability
• App judged highly usable = Go - Proceed with trial (Green)
• App judged usable = Amend - Proceed with changes (Amber)
• App judged possibly usable = Stop – Do not proceed unless changes are possible (Red)

4. Acceptability of 'AsthmaMD' app
Will the app receive a mean score >5 for overall user satisfaction?
• >5 overall satisfaction = Go - Proceed with trial (Green)
• >4 overall satisfaction = Amend - Proceed with changes (Amber)
• <4 overall satisfaction = Stop – Do not proceed unless changes are possible (Red)
Or
Will >30% of participants say yes to 3/5 acceptability-related questions?
• >30% say yes to 3/5 questions = Go - Proceed with trial (Green)
• >30% say yes to 2/5 questions = Amend - Proceed with changes (Amber)
• <30% say yes to <2/5 questions Stop – Do not proceed unless changes are possible (Red)
And
Interpretation of qualitative data from open-ended questions relating to acceptability
• App judged highly acceptable = Go - Proceed with trial (Green)
• App judged acceptable = Amend - Proceed with changes (Amber)
• App judged possibly acceptable = Stop – Do not proceed unless changes are possible (Red)

5. Feasibility of 'AsthmaMD' app
Did ≥30% of participants use the app ≥1 day per week?
• ≥30% used app ≥1 day/week = Go - Proceed with trial (Green)
• ≥25% used app ≥1 day/week = Amend - Proceed with changes (Amber)
• <20% used app ≥1 day/week = Stop – Do not proceed unless changes are possible (Red)
Or
Would ≥30% of participants continue to use the app after the study?
• ≥30% continue to use the app = Go - Proceed with trial (Green)
• ≥25% continue to use the app = Amend - Proceed with changes (Amber)
• <20% continue to use the app = Stop – Do not proceed unless changes are possible (Red)
And
Interpretation of qualitative data from open-ended questions relating to feasibility
• App judged highly feasible = Go - Proceed with trial (Green)
• App judged feasible = Amend - Proceed with changes (Amber)
• App judged possibly feasible = Stop – Do not proceed unless changes are possible (Red)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2020, National University of Ireland, Galway Research Ethics Committee (NUI Galway Research & Innovation Centre, Distillery Rd, Galway, H91 TK33, Ireland; +44 (0)91492147; ethics@nuigalway.ie), ref: 20-Jan-13

Study design
Non-randomized feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asthma

Interventions
'AsthmaMD' was developed by Dr Sam Pejham, a physician and researcher from the University of California San Francisco, Medical School Clinical Faculty. 'AsthmaMD' allows users to log their peak flow meter (PFM) readings, symptoms, triggers, medications, and other notes in the form of a diary and share this data with their physician. It provides a graphical view of PFM and severity, allows users to create customised reminders to take their medication and guides users through their asthma action plan. Finally, the app provides video tutorials on using a peak flow meter, understanding asthma medication, and using 'AsthmaMD'.

Participants are instructed to download the freely available 'AsthmaMD' app at the end of the baseline questionnaire administered by LimeSurvey. Participants are not instructed on how, when, how often or how long to use 'AsthmaMD'; this is at the users' discretion. No other physical or informational materials are provided to participants as part of the intervention. The intervention duration is 2 weeks based on recent feasibility studies of medication adherence and self-management apps, and input from Patient and Public Involvement (PPI) contributors. The researcher contact participants regarding the follow-up questionnaire and reminders about the same via email, no other means of communication are used. Participants can tailor the app to their own personal regime at their discretion, for example, by entering the name and dosage of their medication at any point during the 2 weeks.

Intervention Type
Behavioural

Primary outcome(s)
1. Usability of the app is measured using the System Usability Scale (SUS) at 2-week follow-up
2. Acceptability of the app measured using questions modified from previous feasibility studies of mHealth interventions (Huang et al., 2019; Zhang et al., 2019) at 2-week follow-up
3. Feasibility of the app measured using frequently used questions modified from previous feasibility studies of mHealth interventions (Edbrooke-Childs et al., 2019; Escobar-Viera et al., 2020; Hightow-Weidman et al., 2018; Huang et al., 2019; Zhang et al., 2019) at 2-week follow-up

Key secondary outcome(s))
1. Source of recruitment measured by asking participants how they heard about the study at baseline
2. Attrition measured using the number of participants who consent to participate and who remain in the study until the end of follow-up at 2 weeks
3. Adherence to ICS measured using the Medication Adherence Report Scale for Asthma (MARS-A) at baseline and 2-week follow-up
4. Asthma control measured using the Asthma Control Test (ACT) at baseline and 2-week follow-up

Completion date
31/01/2021

Eligibility

Key inclusion criteria

1. Age between 18-30 years on date of recruitment
2. Diagnosis of asthma
3. Current prescription for any form of ICS
4. Own a smartphone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
18 years

Upper age limit
30 years

Sex
All

Total final enrolment
122

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
21/09/2020

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Ireland

Study participating centre
Galway Family Doctors
Mervue
Galway
Ireland
H91 A8N9

Study participating centre
Turlougmore Medical Centre
Lackagh Beg
Athenry
Galway
Ireland
H65 H599

Study participating centre
Claddagh Medical Centre
The Crescent
Galway
Ireland
H91 EA37

Study participating centre
Kingston Medical Centre
Kingston Hall
Knocknacarra
Galway
Ireland
H91 CH29

Sponsor information

Organisation
National University of Ireland

ROR
https://ror.org/00shsf120

Funder(s)

Funder type
Research council

Funder Name
Irish Research Council

Alternative Name(s)
An Chomhairle um Thaighde in Éirinn, IrishResearch

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. Data will be managed and stored at the School of Psychology at NUI Galway, led by the lead researcher/PhD Candidate, Jane Murphy (j.murphy51@nuigalway.ie). Data will be participant self-report data from the baseline and follow-up questionnaires. Data will be stored indefinitely on a password-protected computer. All data will be anonymised and all participants will have provided informed consent. Data will be analysed only for the aims of this study and completed by the research team at the School of Psychology at NUI Galway, with the lead researcher, Jane Murphy acting as gate-keeper to the data from the password-protected computer.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2021	02/09/2021	Yes	No
Participant information sheet			04/02/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes