# Trial of a digital asthma management application: juli

Submission date	Recruitment status	[X] Prospectively registered
26/05/2021	No longer recruiting	[X] Protocol
Registration date	Overall study status	[X] Statistical analysis plan
08/06/2021	Completed	[X] Results
<b>Last Edited</b> 12/07/2024	Condition category Respiratory	[] Individual participant data
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# Plain English summary of protocol

Background and study aims

Each year, millions of people are diagnosed with asthma and seek additional support via digital applications. It can be overwhelming learning how to manage and unclear what can make symptoms better or worse. The digital health application juli, aims to support people with asthma via a number of evidence based approaches including symptom tracking, medication reminders, journaling, data visualisation of sleep, activity, exercise, oxygen saturation, external data including weather, pollen count and air quality, and heuristic behavioural change technique recommendations about how to improve these parameters.

However, we are still not certain how useful juli is compared to what people may do for themselves to help their asthma. So we are carrying out an eight week, randomised controlled trial of juli to understand if juli is effective in improving asthma control. The primary objective is to investigate whether the juli app is effective in reducing the severity of asthma symptoms, compared to treatment as usual.

### Who can participate?

Participants will be aged 18 - 65 years, are an English speaker, have an iPhone and are suffering from asthma.

# What does the study involve?

Participants will be randomly allocated to receive juli or a dummy version of juli.

The participant will use the app juli for eight weeks, and complete an asthma questionnaire every two weeks (four in total). Participants will also be asked to complete a well-being questionnaire at four and eight weeks and a user satisfaction questionnaire at eight weeks. These are all standardised questionnaires, commonly used for research (the Asthma Control Test, the 12-item Short Form survey of health-related quality of life and the Mobile Health App Usability Questionnaire).

The full version of the app presents the participant with graphical displays of some data automatically generated from their phone and smartwatch. The types of data are: sleep – time in bed and time asleep, activity – steps and flights of stairs climbed, heart rate variability – the

variation in the time interval between heartbeats, workouts – periods of exercise, oxygen saturation and menstrual cycle. It also presents them with external data: weather, pollen count and air quality (provided via geolocation). It asks the participant to rate how they are feeling and answer questions about their asthma control on a daily basis. It allows them to set a medication reminder, and add notes to a journal. It presents them with correlations between these different types of data and helps them to identify things that make their asthma better or worse.

Participants allocated to the dummy version of the app will be asked to rate how they are feeling on a daily basis, but will not have access to the rest of the app.

What are the possible benefits and risks of participating? Some people find it rewarding to take part in medical research and appreciate the additional monitoring. Using juli may improve participants' symptoms of asthma, however, this cannot be guaranteed.

We also hope that by carrying out this study we will help future guidance about when someone is likely to benefit from juli and how we can improve it. There may not be direct benefits of taking part for you. However, the study is designed to improve treatment and increase understanding of asthma.

Where is the study run from?
Division of Psychiatry, University College London (UK)

When is the study starting and how long is it expected to run for? December 2020 to June 2023

Who is funding the study? Juli Health (UK)

Who is the main contact?

Joseph Hayes, joseph.hayes@ucl.ac.uk

# **Contact information**

# Type(s)

Scientific

#### Contact name

Dr Joseph Hayes

#### **ORCID ID**

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# Type(s)

**Public** 

#### Contact name

Mrs Bettina Dührkoop

#### Contact details

juli Health 23 Beach Ave Hull United States of America MA 02045 +44 (0)20 7679 9736 bd@juli.co

# Additional identifiers

# Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Nil known

# Study information

#### Scientific Title

Randomised controlled trial of a digital asthma management application: juli

# **Study objectives**

Use of the juli app reduces asthma symptoms at 8 weeks compared to attention placebo control.

# Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 07/06/2021, UCL Research Ethics (Office of the Vice-Provost (Research), University College London, 2 Taviton St, London, WC1E 6BT, UK; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 19413/001

#### Study design

Interventional placebo-controlled randomized controlled trial

# Primary study design

Interventional

#### Study type(s)

#### **Treatment**

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

Reduction of asthma symptoms in adults with asthma

#### **Interventions**

Use of juli app vs treatment as usual (plus attention placebo control app).

juli app: Participants will be prompted to open the app each day via an automated alert. They will be asked to rate how they are feeling on a scale using 5 emojis and track number of shortness of breath episodes, rescue inhaler usage and night time waking with shortness of breath. The app will gather information via Apple HealthKit; sleep, activity, workouts, oxygen saturation. It will present this data to the participant and show associations with asthma symptoms. It will make recommendations about these parameters to guide healthy behaviours and will use external data sources (weather, air quality, pollen count) to guide these recommendations. The app has a medication reminder function that can be set by the participants to improve medication adherence. Participants are also encouraged to engage in journaling via the app, especially in relation to exacerbating or reliving factors for asthma symptoms.

Attention placebo control app: Participants will be prompted to open the app each day via an automated alert and rate how they are feeling on a scale using 5 emojis.

The participant will use the app for eight weeks and complete an asthma questionnaire every two weeks (four in total). Participants will also be asked to complete a well-being questionnaire at four and eight weeks and a user satisfaction questionnaire at eight weeks.

## Intervention Type

Behavioural

## Primary outcome(s)

Asthma symptoms measured using the Asthma Control Test at 8 weeks

# Key secondary outcome(s))

- 1. Asthma symptoms measured using the Asthma Control Test at 2, 4, and 6 weeks
- 2. Short Form 12 Item health-related quality of life at 4 and 8 weeks

# Completion date

01/08/2023

# **Eligibility**

## Key inclusion criteria

- 1. Asthma with Asthma Control Test score <20 at baseline
- 2. Age 18 to 65 years (inclusive)
- 3. English speaker
- 4. Have an iPhone

#### Participant type(s)

Patient

<b>Healthy volunteers allowed</b> No
<b>Age group</b> Adult
<b>Lower age limit</b> 18 years
<b>Upper age limit</b> 65 years
Sex All
<b>Total final enrolment</b> 152
Key exclusion criteria  1. Asthma Control Test >19 at baseline 2. Children 3. Non-English speakers
Date of first enrolment 21/06/2021
Date of final enrolment 01/06/2023
01/06/2023
01/06/2023  Locations  Countries of recruitment
01/06/2023  Locations  Countries of recruitment United Kingdom
01/06/2023  Locations  Countries of recruitment United Kingdom  England
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O1/06/2023  Locations  Countries of recruitment United Kingdom  England  Afghanistan  Åland Islands
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Anguilla

Antarctica
Antigua and Barbuda
Argentina
Armenia
Aruba
Australia
Austria
Azerbaijan
Bahamas
Bahrain
Bangladesh
Barbados
Belarus
Belgium
Belize
Benin
Bermuda
Bhutan
Bolivia
Bonaire Saint Eustatius and Saba
Bosnia and Herzegovina
Botswana
Bouvet Island
Brazil
British Indian Ocean Territory
Brunei Darussalam

Bulgaria
Burkina Faso
Burundi
Cabo Verde
Cambodia
Cameroon
Canada
Cayman Islands
Central African Republic
Chad
Chile
China
Christmas Island
Cocos (Keeling) Islands
Colombia
Comoros
Congo
Congo, Democratic Republic
Cook Islands
Costa Rica
Croatia
Cuba
Сигаçао
Cyprus
Czech Republic
Côte d'Ivoire

Denmark
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Eswatini
Ethiopia
Falkland Islands
Faroe Islands
Fiji
Finland
France
French Guiana
French Polynesia
French Southern Territories
Gabon
Gambia
Georgia
Germany
Ghana
Gibraltar

Greece
Greenland
Grenada
Guadeloupe
Guam
Guatemala
Guernsey
Guinea
Guinea-Bissau
Guyana
Haiti
Heard Island and McDonald Islands
Holy See (Vatican City State)
Honduras
Hong Kong
Hungary
Iceland
India
Indonesia
Iran
Iraq
Ireland
Isle of Man
Israel
Italy
Jamaica

Japan
Jersey
Jordan
Kazakhstan
Kenya
Kiribati
Korea, North
Korea, South
Kosovo
Kuwait
Kyrgyzstan
Lao People's Democratic Republic
Latvia
Lebanon
Lesotho
Liberia
Libya
Liechtenstein
Lithuania
Luxembourg
Macao
Madagascar
Malawi
Malaysia
Maldives
Mali

Malta
Marshall Islands
Martinique
Mauritania
Mauritius
Mayotte
Mexico
Micronesia, Federated States of
Moldova
Monaco
Mongolia
Montenegro
Montserrat
Могоссо
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands
New Caledonia
New Zealand
Nicaragua
Niger
Nigeria
Niue

Norfolk Island
North Macedonia
Northern Mariana Islands
Norway
Oman
Pakistan
Palau
Palestine, State of
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Pitcairn
Poland
Portugal
Puerto Rico
Qatar
Romania
Russian Federation
Rwanda
Réunion
Saint Barthélemy
Saint Helena, Ascension and Tristan da Cunha
Saint Kitts and Nevis
Saint Lucia



Switzerland
Syria
Taiwan
Tajikistan
Tanzania
Thailand
Timor-Leste
Togo
Tokelau
Tonga
Trinidad and Tobago
Tunisia
Turkmenistan
Turks and Caicos Islands
Tuvalu
Türkiye
Uganda
Ukraine
United Arab Emirates
United States Minor Outlying Islands
United States of America
Uruguay
Uzbekistan
Vanuatu
Venezuela
Viet Nam

Virgin Islands, British Virgin Islands, U.S.

Wallis and Futuna

Western Sahara

Yemen

Zambia

Zimbabwe

Study participating centre
University College London
Division of Psychiatry
6th Floor Maple House
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London
United Kingdom
W1T 7BN

# Sponsor information

# Organisation

University College London

#### **ROR**

https://ror.org/02jx3x895

# Funder(s)

# Funder type

Industry

## **Funder Name**

juli Health

# **Results and Publications**

# Individual participant data (IPD) sharing plan

Data will only be available to approved University College London researchers. The data will be available from Joseph Hayes (joseph.hayes@ucl.ac.uk). The data will be available following the publication of the trial and will include outcome measures and baseline characteristics. Participants have consented to: "I understand that other UCL authenticated researchers will have access to my anonymised data." They may endorse: "If you would like your contact details to be retained so that you can be contacted in the future by UCL researchers who would like to invite you to participate in follow-up studies to this project, or in future studies of a similar nature, please tick the appropriate box below."

## IPD sharing plan summary

Available on request

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/04/2024	12/07/2024	Yes	No
Participant information sheet	version V4		08/07/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		23/07/2023	09/08/2023	No	No
Protocol file	version v2.0		08/07/2021	No	No
Statistical Analysis Plan		08/07/2021	09/08/2023	No	No