

# Trial of a digital asthma management application: juli

<b>Submission date</b> 26/05/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/06/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/07/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## 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

<https://orcid.org/0000-0003-2286-3862>

### Contact details

6th Floor Maple House

149 Tottenham Court Road

London

United Kingdom

W1T 7BN

+44 (0)20 7679 9736

joseph.hayes@ucl.ac.uk

**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

**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

### Healthy volunteers allowed

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

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

**Locations****Countries of recruitment**

United Kingdom

England

Afghanistan

Åland Islands

Albania

Algeria

American Samoa

Andorra

Angola

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  
Curaçao  
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

Morocco

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

Saint Martin (French part)

Saint Pierre and Miquelon  
Saint Vincent and the Grenadines  
Samoa  
San Marino  
Sao Tome and Principe  
Saudi Arabia  
Senegal  
Serbia  
Seychelles  
Sierra Leone  
Singapore  
Sint Maarten (Dutch part)  
Slovakia  
Slovenia  
Solomon Islands  
Somalia  
South Africa  
South Georgia and the South Sandwich Islands  
South Sudan  
Spain  
Sri Lanka  
Sudan  
Suriname  
Svalbard and Jan Mayen  
Sweden  
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  
149 Tottenham Court Road  
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?
<a href="#">Results article</a>		29/04/2024	12/07/2024	Yes	No
<a href="#">Participant information sheet</a>	version V4		08/07/2021	No	Yes
<a href="#">Preprint results</a>		23/07/2023	09/08/2023	No	No
<a href="#">Protocol file</a>	version v2.0		08/07/2021	No	No
<a href="#">Statistical Analysis Plan</a>		08/07/2021	09/08/2023	No	No