

Trial of a digital depression management application: juli

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

Plain English summary of protocol

Background and study aims

Each year, millions of people are diagnosed with depression and seek additional support from digital applications (apps). 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 depression with a number of evidence-based approaches including symptom tracking, medication reminders, journaling, data on sleep, activity, exercise, oxygen levels and heart rate, and recommendations about how to improve these.

However, it is still not certain how useful juli is compared to what people may do for themselves to help their depression. The aim of this study is to find out whether juli is effective at improving depression symptoms, compared to treatment as usual.

Who can participate?

People aged 18-65 years with depression

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 for 8 weeks, and complete a depression symptoms questionnaire every 2 weeks (four in total). Participants will also be asked to complete a wellbeing questionnaire at 4 and 8 weeks and a user satisfaction questionnaire at 8 weeks. These are all standardised questionnaires, commonly used for research.

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 (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 mood 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 mood 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 depression, but this cannot be guaranteed.

It is also hoped that carrying out this study will help future guidance about when someone is likely to benefit from juli and how it can be improved. There may not be direct benefits of taking part. However, the study is designed to improve treatment and increase understanding of depression.

Where is the study run from?

University College London (UK)

When is the study starting and how long is it expected to run for?

December 2020 to August 2023

Who is funding the study?

Juli Health (USA)

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

2

Study information

Scientific Title

Randomised control trial of a digital depression management application: juli

Acronym

juli

Study objectives

Use of the juli app reduces depression 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 Committee (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

Depression

Interventions

Participants will be randomly allocated using an online tool to receive the juli app or treatment as usual plus an attention placebo control app.

The participant will use the juli app for 8 weeks and complete a depression symptoms questionnaire every 2 weeks (four in total). Participants will also be asked to complete a wellbeing questionnaire at 4 and 8 weeks and a user satisfaction questionnaire at 8 weeks. These are all standardised questionnaires, commonly used for research (the 8-item Patient Health Questionnaire, 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:

1. Sleep – time in bed and time asleep
2. Activity – steps and flights of stairs climbed
3. Heart rate variability – the variation in the time interval between heartbeats
4. Workouts – periods of exercise
5. Oxygen saturation
6. 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 mood 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 mood 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.

Intervention Type

Behavioural

Primary outcome(s)

Depression symptoms measured using the eight-item Patient Health Questionnaire (PHQ-8) at 8 weeks

Key secondary outcome(s)

1. Depression symptoms measured using the PHQ-8 at 2, 4 and 6 weeks
2. Health-related quality of life measured using Short Form 12 (SF-12) Item at 4 and 8 weeks

Completion date

01/08/2023

Eligibility

Key inclusion criteria

1. Depression with PHQ-8 score >4 at baseline
2. Age 18 to 65 years (inclusive)
3. English speakers
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

456

Key exclusion criteria

1. PHQ-8 <5 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?
Results article		07/06/2024	12/07/2024	Yes	No
Participant information sheet	version V4		08/07/2021	No	Yes
Preprint results		11/04/2023	06/07/2023	No	No
Protocol file	version V2.0		08/07/2021	No	No
Statistical Analysis Plan	version 2.0		06/07/2023	No	No