ISRCTN12329547 https://doi.org/10.1186/ISRCTN12329547

Trial of a digital depression management application: juli

Submission date
26/05/2021

Recruitment status
No longer recruiting

Registration date
08/06/2021

Overall study status
Completed

Last Edited
12/07/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
See additional files

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

Secondary outcome measures
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

Overall study start date

01/12/2020

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
476

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
Afghanistan

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

England

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 Kingdom

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

Åland Islands

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

Sponsor details

Division of Psychiatry
London
England
United Kingdom
WC1E 6BT
+44 (0)207 679 9253
Glyn.lewis@ucl.ac.uk

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Juli Health

Results and Publications

Publication and dissemination plan
When the study is completed, the results will be published in a peer-reviewed healthcare journal so healthcare professionals can see the results.

Intention to publish date
01/12/2023

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