Effects of different coffee recipes on mental health performance in community adults

Submission date	Recruitment status	Prospectively registered
14/10/2022	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/11/2022	Completed	☐ Results
Last Edited	Condition category	Individual participant data
07/11/2022	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Background and study aims

Coffee is good for health as known worldwide, and the smell of coffee aroma and the mixture of a number of bio-natural compounds such as antioxidant polyphenols can alleviate participants' depression symptoms in some studies. Darker roasted coffee beans have a stronger coffee aroma and fewer polyphenols. The aim of this study is to determine the effects of different coffee recipes on mental health performance in adults.

Who can participate?

Healthy working adults aged over 22 years

What does the study involve?

Participants are randomly allocated into two equal groups. Group A drinks Recipe A coffee and Group B drinks Recipe B coffee (200 ml before noon three times a week for 12 weeks).

What are the possible benefits and risks of participating?

By participating in this study, participants get free three drip coffee bags a week for 3 months. Completing an online survey related to mental health may be distressing. Participants can pause to drink the coffee beverages during the study or withdraw entirely if they wish.

Where is the study run from?

- 1. National Association of Small & Medium Enterprise, R. O. C. (Taiwan)
- 2. Chiayi Campus of Chang Gung University of Science and Technology (Taiwan)
- 3. Chi Mei Medical Center (Taiwan)

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

Who is funding the study?

This study/project is funded by the Chronic Diseases and Health Promotion Research Center, Chang Gung University of Science, Chiayi Campus of Chang Gung University of Science and Technology (CGUST) (Taiwan)

Who is the main contact?
Dr Chia-Hsiu Chang
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Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Effects of different coffee recipes on mental health performance in community adults

Acronym

CGA

Study objectives

- 1. Caffeine and chlorogenic acid levels are an effective energy booster that can improve mental health performance in adults
- 2. Trigonelline can also improve the mental health performance of adults

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/07/2020, Chang Gung Medical Foundation Institutional Review Board (No. 199, Dunhua N. Rd., Songshan Dist., 105 Taipei City, Taiwan (R.O.C.); +886-33196200#3716; yijiun@cgmh.org.tw), ref: 202000636A3D001

Study design

Multicenter interventional double-blind randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please contact the investigator, Chia- Hsiu, Chang, email address: chchang01@mail.cgust.edu.tw.

Health condition(s) or problem(s) studied

Mental health

Interventions

Participants were randomly allocated into two equal groups through a random lottery by researchers.

Group A ingested Recipe A 200 ml coffee drink with 5 g dark roasted Ethiopian coffee beans (Arabica Variety: Original) mixed with 5 g light roasted Colombian Arabica coffee beans (Arabica Variety: Bourbon and Typica).

Group B ingested Recipe B 200ml coffee drink with 4 g dark roasted Ethiopian coffee beans mixed with 6 g light roasted Colombian coffee beans.

The Short Portable Mental Status Questionnaire (SPMSQ) was used to measure cognitive status for all participants, and the 5-item Brief Symptom Rating Scale (5-BSRS) was used to evaluate the difference between baseline and post-test for mental health performance in 58 adults.

The coffee beans in the study were roasted by a roaster who was certificated by the Specialty Coffee Association of America. After grinding, two recipes of coffee beans were packaged in drip bags. All the participants were required to obey the process as follows: pouring 200 ml 97°C hot water into the coffee drip bags with a cup and having coffee beverages three times a week before 12:00 at noon for 12 weeks.

Intervention Type

Other

Primary outcome measure

- 1. Cognitive status measured using SPMSQ at pretest (baseline) and posttest (12 weeks later)
- 2. Mental health assessed using 5-BSRS at pretest (baseline) and posttest (12 weeks later)

Secondary outcome measures

- 1. Coffee content of caffeine, 4-O-caffeoylquinin acid, chlorogenic acid (CGA), 5-O-caffeoylquinic acid, and trigonelline measured using high-performance liquid chromatography (HPLC) at posttest (12 weeks later)
- 2. Coffee content of 1-methy-2-pyrrolidone, CNMP, 2,5-dimethylpyrazine measured using gas chromatography at posttest (12 weeks later)

Overall study start date

22/04/2020

Completion date

01/03/2021

Eligibility

Key inclusion criteria

- 1. Willing to sign a written participant consent form
- 2. Male and female subjects currently working
- 3. Normal SPMSQ test
- 4. Men and women over the age of 22 years

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

60

Total final enrolment

58

Key exclusion criteria

- 1. Pregnant women or patients with osteoporosis
- 2. Major surgery within 14 days
- 3. Currently suffering from disease and in the acute phase

Date of first enrolment

20/08/2020

Date of final enrolment

21/08/2020

Locations

Countries of recruitment

Taiwan

Study participating centre Chiayi Campus of Chang Gung University of Science and Technology

No.2, Sec. W. Jiapu Rd Puzi City Taiwan

61363

Study participating centre

National Association of Small & Medium Enterprise, R. O. C.

6F., No. 95, Sec. 2 Roosevelt Rd Da'an Dist Taipei City Taiwan 10646

Study participating centre

Chi Mei Medical Center

No.901, Zhonghua Rd Yongkang Dist Tainan City Taiwan 71004

Sponsor information

Organisation

Chang Gung University of Science and Technology

Sponsor details

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Sponsor type

University/education

Website

https://cdhprc.cgust.edu.tw/

ROR

https://ror.org/009knm296

Funder(s)

Funder type

University/education

Funder Name

Chronic Diseases and Health Promotion Research Center, Chang Gung University of Science and Technology

Results and Publications

Publication and dissemination plan

- 1. Planned publication in a peer-reviewed journal
- 2. Study protocol and statistical analysis plan will be available when they are completed

Intention to publish date

01/12/2022

Individual participant data (IPD) sharing plan

After the primary results have been published, the individual participant data (IPD) and associated documentation, including the protocol and statistical analysis data, will be prepared to be shared with other researchers. The people who request access to the IPD will be reviewed by all researchers following the CGUST policy on data sharing. Please contact Dr Chia-Hsiu Chang (chchang01@mail.cgust.edu.tw) for general project enquiries and participant-level data. We can offer the data approved by the participants and delinked personal data after the article has been published for 3 years.

IPD sharing plan summary

Available on request