

Study on the benefits of dark chocolate and its association with laboratory measurements and quality of life

Submission date 12/08/2026	Recruitment status Not yet recruiting	☒ Prospectively registered ☐ Protocol
Registration date 14/08/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 12/08/2026	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

The consumption of certain amounts of cocoa products and specifically dark chocolate may be beneficial for the human body, which can be related with the outcome of specific diseases and with laboratory markers. In addition, it has been reported to affect other aspects such as self-reported quality of life and perceived stress. The aim of this study is to investigate the influence of dark chocolate consumption on laboratory markers included in regular preventive laboratory screening as well as on perceived stress and quality of life.

Who can participate?

Attendees of the Biopathology Laboratory of the General Hospital of Agios Nikolaos (GNAN), aged 25-55 years, who visit the laboratory for routine testing

What does the study involve?

Study participants will be randomly assigned to one of two study groups, the intervention group or the control group. Those participating in the intervention group, will be asked to consume 40 grams of dark chocolate (70%) per day (20 g in the morning and 20 g in the evening) for up to 16 weeks, while the control group will not receive any cocoa product or placebo. Both groups will be asked to participate in laboratory blood tests upon enrollment in the study and 16 weeks after their enrollment.

In addition, participants will be asked to complete surveys at study entry and at 8 and 16 weeks after entry. Body measurements such as BMI and waist circumference will also be collected three times, as previously described. Furthermore, socio-demographic characteristics and health habits will be documented. Individuals included in the study will be thoroughly informed before their enrollment.

The study will take place in the Biopathology Laboratory of the General Hospital of Agios Nikolaos, Crete, Greece and total participation time is 16 weeks.

What are the possible benefits and risks of participating?

There are no known risks associated with this study. However, one possible inconvenience may be the time required to complete the study. Furthermore, in the event that any unexpected

findings occur and any laboratory measurement is found outside the normal range, participants will be notified, if they wish, immediately so that they can inform their personal physician. The commercial dark chocolate product that will be used will be an approved product for distribution in Greece, where all the ingredients it contains will be listed on its packaging and the participants included in the intervention group will be informed in detail about these ingredients before consuming it.

It is not certain that there will be any direct benefits from the participation in this research. However, one direct benefit that may arise concerns the conduct of preventive regular check-ups that may help in the early diagnosis and treatment of diseases that are not yet diagnosed and in the collection of health information with the aim of a more complete personal file. Nevertheless, participants' contribution to the study is important because there will be an opportunity to investigate the effects of dark chocolate intake (70% cocoa) on physical and mental health, nutrition, and laboratory markers. There will be no personal compensation for participation in the study.

Where is the study run from?

General Hospital of Agios Nikolaos (Greece)

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

February 2027 to August 2027

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Contact information

Type(s)

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Additional identifiers**Study information****Scientific Title**

Investigation of the benefits of dark chocolate consumption and its association with laboratory health indicators and quality of life: an interventional study

Study objectives

The objectives of the study are:

1. To investigate the effect of dark chocolate consumption (70% cocoa) on laboratory indicators included in regular preventive screening
2. To explore its influence on perceived stress and quality of life
3. To study the possible differences in the aforementioned variables between the intervention group and the control group
4. To detect multivariate associations with socio-demographic variables, health habits, health condition, and anthropometric measurements
5. To assess the levels of mindful eating behavior and adherence to the Mediterranean diet
6. To investigate the effect of the recommended amount of dark chocolate on quality of life, perceived stress, and anthropometric data, as questionnaires and corresponding measurements will be recorded upon each participant's entry into the study and 8 and 16 weeks after

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/03/2026, Research Ethics Committee of the University of Crete (Voutes Campus, Rector's Office Building, Heraklion, 70013, Greece; +30 2810 393189; ehde@uoc.gr), ref: 71/30.03.2026

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Parallel

Purpose

Evidence-based complementary care with a nutritional supplement to support health and well being

Study type(s)**Health condition(s) or problem(s) studied**

Healthy individuals

Interventions

The present research will follow the design of an intervention study with a control group, in which no intervention will be performed. For the intervention group, 40 grams of dark chocolate (70%) per day (20g in the morning and 20g in the evening) will be administered for up to 16 weeks, while the control group will not receive any cocoa product or placebo. For the intervention and control groups, laboratory blood tests will be performed at baseline and 16 weeks after each participant's enrolment. The completion of the Short Form-12 Health Survey (SF-12), Mindful Eating Behaviour Scale – Trait (MEBS-T), 14-Item Mediterranean Diet Adherence Screener (MEDAS), and Perceived Stress Scale-14 (PSS-14) as well as anthropometric data will also be obtained at baseline and 8 and 16 weeks after each participant's enrolment. A random allocation ratio will be used for the recruitment of the patients in the intervention and control group, taking into account age and gender.

Intervention Type

Other

Primary outcome(s)

1. Complete blood count (CBC) measured using Abbott Alinity hq hematology analyzer based on impedance technology, optical light scatter analysis, and flow cytometric techniques at baseline and 16 weeks post-entry
2. White Blood Cell Count (WBC) measured using Abbott Alinity hq hematology analyzer based on impedance technology, optical light scatter analysis, and flow cytometric techniques at baseline and 16 weeks post-entry
3. Serum glucose (GLU) measured using hexokinase enzymatic method at baseline and 16 weeks post-entry
4. Total cholesterol (TC) measured using the cholesterol oxidase-peroxidase (CHOD-POD) enzymatic colorimetric method at baseline and 16 weeks post-entry
5. High-density lipoprotein cholesterol (HDL-C) measured using direct homogeneous enzymatic assay at baseline and 16 weeks post-entry
6. Triglycerides (TGs) measured using the glycerol-3-phosphate oxidase-peroxidase (GPO-POD) enzymatic colorimetric method at baseline and 16 weeks post-entry

7. Low-density lipoprotein cholesterol (LDL-C) measured using the Friedewald equation when applicable at baseline and 16 weeks post-entry
8. C-reactive protein (CRP) measured using the particle-enhanced immunoturbidimetric assay at baseline and 16 weeks post-entry
9. Serum insulin concentrations measured using the chemiluminescent microparticle immunoassay (CMIA) on an Abbott ARCHITECT immunoassay analyzer at baseline and 16 weeks post-entry
10. Serum cortisol concentrations measured using the chemiluminescent microparticle immunoassay (CMIA) on an Abbott ARCHITECT immunoassay analyzer at baseline and 16 weeks post-entry

Key secondary outcome(s)

1. Quality of life measured using the Short Form-12 Health Survey at study entry and at 8 and 16 weeks post-entry
2. Perceived stress measured using the Perceived Stress Scale-14 (PSS-14) at study entry and at 8 and 16 weeks post-entry
3. Mindful nutrition measured using the Mindful Eating Behavior Scale – Trait (MEBS – T) at study entry and at 8 and 16 weeks post-entry
4. Adherence to the Mediterranean diet measured using the 14-Item Mediterranean Diet Adherence Screener (MEDAS) at study entry and at 8 and 16 weeks post-entry

Completion date

20/08/2027

Eligibility

Key inclusion criteria

1. Attendees at the Biopathology Laboratory of Agios Nikolaos General Hospital who will be coming for regular check-up laboratory measurements
2. Aged between 25 and 55 years old

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

25 Years

Upper age limit

55 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Individuals who do not belong to the age group of 25-55 years old
2. Individuals who have taken dietary supplements or other sources of flavonoids (multivitamins, flavonoids) during the last month
3. Individuals with chronic diseases or metabolic disorders (diabetes, cardiovascular diseases, autoimmune diseases)
4. Individuals with diagnoses of major mental disorders (depression, anxiety disorder, etc) or who are taking medication for psychiatric diseases
5. Individuals with minimal or excessive physical activity. Individuals with moderate physical activity (3-5 times a week, 30 minutes at a time) will be able to participate
6. Individuals with an allergy or intolerance to chocolate, its ingredients, or other related substances
7. Individuals who are pregnant or breastfeeding

Date of first enrolment

01/02/2027

Date of final enrolment

20/04/2027

Locations

Countries of recruitment

Greece

Sponsor information

Organisation

University of Crete

ROR

<https://ror.org/00dr28g20>

Funder(s)

Funder type

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available