ISRCTN12142581 https://doi.org/10.1186/ISRCTN12142581

# Clinical study to assess if a food supplement can help reduce cellulite and support body slimming in women

**Submission date**
21/11/2025

**Recruitment status**
No longer recruiting

**Registration date**
26/11/2025

**Overall study status**
Ongoing

**Last Edited**
25/11/2025

**Condition category**
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Cellulite is a very common condition that affects around 80–90% of women after puberty. It causes the skin, especially on the thighs, hips and buttocks, to look uneven or dimpled, often described as an “orange peel” appearance. Although it is not a disease, cellulite can have a strong impact on how women feel about their bodies, sometimes reducing self-confidence and quality of life.
The causes of cellulite are complex and can include hormones, genetics, age, circulation problems and lifestyle factors.
Current treatments such as creams or aesthetic devices usually have limited or short-term results and can be expensive or time-consuming.
A French company, Activ’Inside, has developed a new food supplement called Celluvine™, which combines grape extract, Coenzyme Q10 (CoQ10) and vitamin C. These ingredients may help improve skin firmness, reduce oxidative stress, support collagen production and improve circulation.
A previous small study showed promising results in reducing cellulite appearance and body weight, but more evidence is needed.
This clinical study aims to test whether Celluvine™ can help improve the visible appearance of cellulite and support body slimming in overweight women, compared to a placebo (a capsule with no active ingredient).

Who can participate?
Healthy women aged between 25 and 45 years who are overweight and have moderate cellulite on their thighs and buttocks can take part in the study.

What does the study involve?
Participants will be asked to give their written informed consent before taking part in any study activity.
They will take part in the study for about 12 weeks (around 3 months) and will attend three visits at the study centre: at the beginning (baseline), after 56 days, and after 84 days.
Before starting the supplement, each participant will meet a qualified dietitian who will prepare

a personalized diet plan with a normal calorie intake. This diet will be followed for two months before starting the product (either the active supplement or placebo) and will be maintained during the study.
Participants will be asked to follow their assigned diet and record any changes in their eating habits or physical activity in a daily diary, and to take part in several measurements and assessments, including:
1. Cellulite Severity Scale (CSS)
2. Measurements of waist, hip, and thigh circumferences
3. Evaluation of skin microcirculation in cellulite areas
4. Measurements of body weight, BMI, and fat mass
5. Assessment of skin waviness and surface profile, blood flow rate, and 3D skin imaging using the PRIMOS-CR® system
6. Allow digital photographs to be taken of the affected skin areas.
7. Complete a self-assessment questionnaire at the final visit to report their personal impressions and perceived changes.

What are the possible benefits and risks of participating?
The food supplement tested in this study meets all current food safety regulations and is made of ingredients that are already known to be safe for human use.
No side effects are expected when used as directed. However, as with any food product, there is always a small possibility that some people may experience an individual reaction. Before taking part, participants will be informed if the product contains any substances that could cause allergic or sensitivity reactions.
The possible benefits of taking part in the study include an improvement in the appearance of cellulite and support for body slimming.

Where is the study run from?
Complife Italia S.r.l. (Italy)

When is the study starting and how long is it expected to run for?
July 2025 to July 2026

Who is funding the study?
Activ'Inside (France)

Who is the main contact?
Dr Roberta Villa, roberta.villa@complifegroup.com

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Enza Cestone

### Contact details
Via Guido Rossa, 1
Garbagnate Milanese (MI)
Italy
20024

+39 (0)38225504
info@complifegroup.com

### Type(s)
Public, Scientific

### Contact name
Dr Roberta Villa

### Contact details
Viale Indipendenza, 11
Pavia (PV)
Italy
27100
+39 (0)38225504
roberta.villa@complifegroup.com

## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
H.E.HU.HV.NAC00.060.09.00_IT0006420/25

## Study information

### Scientific Title
Clinical evaluation of the efficacy of a food supplement in improving cellulite appearance and supporting body slimming: a randomized, double-blind, placebo-controlled study

### Acronym
CELLSLIM

### Study objectives
The primary objective of this study is to evaluate the efficacy of the product in improving cellulite appearance. The secondary objective of this study is to assess the slimming effect of the product, as part of a controlled dietary regimen.

### Ethics approval required
Ethics approval required

### Ethics approval(s)

approved 12/11/2025, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), 20020, Italy; +39 (0)97592449; secretariat@ieicommittee.com), ref: IC001A

## Study design
Double-blind randomized parallel-group placebo-controlled trial

## Primary study design
Interventional

## Study type(s)
Efficacy, Treatment

## Health condition(s) or problem(s) studied
Overweight female subjects with moderate cellulite on thighs and buttocks

## Interventions
The product under investigation is Celluvine™, a food supplement that contains ingredients with antioxidant and skin-supporting activity. Half of the recruited subjects are randomized to receive the active product, while the other half receive the placebo. A restricted randomization list is generated by an independent technician using the appropriate algorithm (Wey's urn) implemented in PASS 11 software (PASS, LLC, Kaysville, UT, USA) and stored in a secure location. The principal investigator or a designated delegate dispenses the investigational products according to the randomization list.
The study is conducted as a double-blind trial: subjects, investigators, and collaborators are blinded to product allocation. Both the active and placebo products are provided in identical packaging, with no distinguishable differences between them.
Subjects take the assigned treatment for 84 ± 2 days as follows: one capsule per day, by oral route, in the morning, with a glass of water.

## Intervention Type
Supplement

## Primary outcome(s)
1. Hexsel Cellulite Severity Scale (CSS) (score from 1 to 15) at baseline, and after 56 days and 84 days of treatment
2. Cellulite-induced alteration of skin microcirculation (score from 0 to 3) at baseline, and after 56 days and 84 days of treatment
3. Blood flow rate (P.U.) measured using the laser Doppler technique with the Periflux 6000 device (Perimed) at baseline and after 84 days of treatment
4. Maximum height of waviness of skin surface profile (µm) measured using PRIMOS-CR® at baseline and after 84 days of treatment

## Key secondary outcome(s))
1. Waist circumference (cm) measured using a tape at baseline, and after 56 days and 84 days of treatment
2. Hip circumference (cm) measured using a tape at baseline, and after 56 days and 84 days of treatment
3. Thigh circumference (cm) measured using a tape at baseline, and after 56 days and 84 days of treatment
4. Body weight (kg) measured using a scale at baseline and after 84 days of treatment

5. Body Mass Index (BMI) (kg/m²) calculated as BMI = weight (kg) / height² (m²) at baseline and after 84 days of treatment
6. Fat mass (kg) measured using the BIA 101 ASE device (Bioelectrical Impedance Analysis) at baseline and after 84 days of treatment
7. Self-evaluation questionnaire: consists of 12 multiple-choice questions assessing perceived efficacy and product pleasantness, administered after 84 days of treatment

### Completion date
08/07/2026

## Eligibility

### Key inclusion criteria
1. Healthy female subjects
2. Subjects of Caucasian ethnicity
3. Subjects aged between 25 and 45 years (extremes included)
4. Subjects who are overweight*
5. Subjects with moderate cellulite on thighs and buttocks**
6. Subjects registered with National Health Service (NHS)
7. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
8. Subjects able to understand the language used in the investigation centre and the information given by the investigator or designated personnel
9. Subjects able to respect the instructions given by the investigator or designated personnel as well as able to respect the study constraints and specific requirements
10. Subject who commit not to change their daily routine or lifestyle during the study
11. Subject who commit to follow a normocaloric diet developed by a professional dietitian***
12. Subjects on stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) for at least one month without any changes expected or planned during the study
13. Subjects informed about the test procedures who have signed a consent form and privacy agreement

* BMI between 25 kg/m2 and 29.9 kg/m2. According to the World Health Organization (WHO) BMI Classification.
** At recruitment, Hexsel Cellulite Severity Scale (CSS) scores from 6 to 10.
*** Subjects will adhere to a controlled normocaloric dietary regimen starting two months prior to product intake. Each participant will undergo a visit with a qualified dietitian, who will design a personalized daily diet plan based on the individual’s estimated energy requirements. The prescribed diet will be individualized to ensure energy balance, without inducing weight loss or gain, in order to control for potential confounding effects of caloric intake on study outcomes. Throughout the study, participants will keep a weekly diary to record their dietary adherence (i. e., whether they followed the assigned plan or made any changes) as well as their physical activity

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
Yes

## Age group
Adult

## Lower age limit
25 years

## Upper age limit
45 years

## Sex
Female

## Total final enrolment
0

## Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subjects who are menopausal or perimenopausal
3. Subjects who are smokers
4. Subjects with any acute, chronic, or progressive disease or condition that may interfere with the study data or that the investigator considers dangerous to the subject or incompatible with the requirements of the study ****
5. Subjects participating or planning to participate in other clinical trials
6. Subjects who participated in a similar study without respecting an adequate washout period (at least one month)
7. Subjects that have food intolerances or food allergies to ingredients of the study product
8. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator *****
9. Subjects who are currently using food supplement(s) and/or products with the same activity as the study product, or who haven't observed an adequate washout period (at least one month)
10. Subjects admitted to a health or social facility
11. Subjects planning a hospitalization during the study
12. Subjects not able to be contacted in case of emergency
13. Subjects deprived of freedom by administrative or legal decision or under guardianship
14. Subjects who have or have had a history of alcohol or drug addiction
15. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc)
16. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential).

**** Steroids including topical steroids, cytostatics, vasodilators, diuretics, anticoagulants, chemotherapeutics, drugs for obesity; biological drugs; immunosuppressants.
***** chronic disease (blood circulation, cardio-vascular, diabetes, lipedema, psychiatric, neuro-degenerative, cancer, liver, gastric, skin, etc.); favism; history of bariatric surgery (gastric bypass, sleeve gastrectomy, gastric band and duodenal switch.

## Date of first enrolment
12/11/2025

## Date of final enrolment
07/01/2026

# Locations

**Countries of recruitment**
Italy

**Study participating centre**
**Complife Italia S.r.l.**
Via Monsignor Angelini, 21
San Martino Siccomario (PV)
Italy
27028

**Study participating centre**
**Complife Italia S.r.l.**
Via Signorelli, 159
Garbagnate Milanese (MI)
Italy
20024

**Study participating centre**
**Complife Italia S.r.l.**
Piazzale Siena, 11
Milano (MI)
Italy
20146

# Sponsor information

**Organisation**
Activ'Inside

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Activ'Inside

# Results and Publications

### Individual participant data (IPD) sharing plan
Stored in non-publicly available repository.
Published as a supplement to the results publication.

### IPD sharing plan summary
Published as a supplement to the results publication, Stored in non-publicly available repository