Health claim’s assessment process of herbs as supplemented food or functional ingredient for food in Taiwan

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President, International Society for Nutraceuticals and Functional Foods
Former President, Chung Shan Medical University

A case study workshop: Health claim’s regulatory assessment process
4 April 2018
Winsor suites hotel, Sukhumvit, Bangkok, Thailand

Junction for the health and preventive medicine of the functionality of agricultural and foods

Non-communicable diseases (life style) and Health!

CAM (complementary and alternative medicine): 1997, NCCAM (national center of CAM, USA)
Non-communicable diseases and health

The World Declaration of Nutrition and Global Plan of Action: Highlights
Rome 1992

- Everyone has right to get nutrition and safe food.
- Nutrition is closely associated with social development and is also the target of human progress.
WHO/WHA 57
Resolution and strategy

GLOBAL STRATEGY
ON DIET, PHYSICAL
ACTIVITY AND HEALTH

In May 2004, the 57th World Health Assembly (WHA) endorsed the World Health Organization (WHO) Global Strategy on Diet, Physical Activity and Health. The strategy was developed through a wide-ranging process of consultation with all concerned stakeholders in response to a request from Member States at World Health Assembly 2002 (Resolution WHA55.25).

The Strategy, together with the Resolution by which it was endorsed, are outlined in this document.

Nutrition deficiency and Health

- Overweight & Obesity
- Low vegetables, fruits and dairy intake
- Low Vit B1, B2, B6, folic acid, Mg, K
- Low calcium
- High protein and lipid and low CHO
- High sweet drink and fried food
- Nutritional education and environment
What is Nutrition?

- Vitamins, minerals?
- Carbohydrates, Lipids, Proteins?
- Phytochemicals?
- Nutritional supplement?
- Functional foods?
- Herbs?

For Health......!!
From individual to community, education, policy

Chance for agricultural and foods

- CAM as a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine (also called Western or allopathic medicine)
- herb, acupuncture, magnetic treatment, functional foods, nutraceuticals — evidence based (safety and effectiveness)
### Market status of functional food in USA, Europe and Japan

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>Europe</th>
<th>Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketing (USD)</td>
<td>26.18 billion</td>
<td>24.64 billion</td>
<td>19.25 billion</td>
</tr>
<tr>
<td>Points from consumers</td>
<td>What an ingredient does</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dietary supplements</td>
<td>Dietary Supplement Health and Education (1994)</td>
<td>X</td>
<td>Health food Manufacturers Association</td>
</tr>
<tr>
<td>Approved</td>
<td>X</td>
<td>X</td>
<td>V</td>
</tr>
<tr>
<td>Health benefits</td>
<td>Heart health and body weight reduction</td>
<td>Immune, digestion</td>
<td>Immune and digestion</td>
</tr>
<tr>
<td>Popular materials and products</td>
<td>Vitamins, minerals, plant extracts</td>
<td>Probiotics, dietary fiber</td>
<td>Dietary fiber, specific proteins</td>
</tr>
<tr>
<td>Major types</td>
<td>Bar, cereal, drink</td>
<td>Dairy, drink</td>
<td>Special oils</td>
</tr>
</tbody>
</table>


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### Herbs allow to be used as food in Taiwan

According to the "discretionary staging" principle, so far has announced 215 kinds of "can provide food use of Chinese herbal medicines" items in Taiwan, as the following:

- **Vegetables**: lily, lotus leaf, tremella, yam, ginger, lettuce, laminaria, leek (not including seeds), onion, xiebai, hu (Garlic), brassica (rapeseed), (cabbage), mustard, white mustard (does not contain seeds), turnip (speedwell), sulfuraphane (radish) (not containing seeds), celery, chrysanthemum, coriander, carrot, basil, fragrant (anise), dill (cumin), pineapple, chayote, alfalfa, amaranth, portulaca oleracea, lettuce, cucumber, cucumber, taro, taro, gan chilp, bamboo shoots, sour bamboo shoots, grass-stone silkworm, eggplant, kettle loiu, wax gourd (does not contain seeds), pumpkin, zucchini, loofah, balsam pear, laver, stone flower, gelidium, carrageenan, dragon vegetable, lotus root, garlic (small garlic) burdock (root), furry loiu (goose intestines vegetable), jew’s ear, mustard, champignon, seaweed, konnyaku.

- **Fruit**: longan pulp, prune, olive, medlar, plum, peach (not including seeds), chestnut, jujube, pear, mountain zha, ann pomegranate, tangerine, citrus, orange, pomelo, citric, kumquat, loquat, cherry, litchi (not including seeds), longan (without seeds), long hai, olive, coconut, pineapple luo mi, fig, Qin Yu (Pepper, peppers, tea, melon, watermelon, grapes, peach, sugarcane, sugar, red and white lotus, Ji (water chestnut), gorgon, oolong, apricot (fruit), persimmon, red dates.

- **Grains**: soybean, sesame, pine nut, walnut, mung bean, malt, flax, flax, wheat, barley (not including barley bud), buckwheat, Rice, japonica, indica (early rice), millet, millet, maize, Shu (glutinous), yellow soybeans, white beans, peas, cowpea, soya beans, tofu, rice, porridge, rice cakes, dumpings, steam cake, caramel, sauces, vinegar, wine, soju, wine, rice, lotus seeds, Chixiaodou (red beans), oat, broad bean, chestnut, salt, cox seed, black beans.

- **Fish, clam, shrimp, crab**: mussels, oysters (shells), snakehead fish, carp, trout, carp fish (grass carp), mussels, crucian carp, perch, shank, grouper, goldfish, puffer fish, sturgeon, eel fish, catfish (catfish), yellow croaker, dolphin fish, flounder, mackerel, squid, octopus, shrimp, abalone, roe, turtle, crab, clams.

- **Animals**: ragweed, dogs, sheep, gazelle, ox, horse, donkey, mule, yak, yak, wild horse, wild boar, goat, deer, rabbit, chicken, partridge, bamboo chicken, quail, pigeon, finch, turtle dove, shrike, ostrich, pheasant.

- **Other categories**: chrysanthemum, honey, yellow essence, mint, milk, gynostemma pentaphyllum, Cassia seed, Dendrobium, tangerine peel, nutmeg, grass cardamom, flower, anise, ginseng flowers.
Potential Herbs (45 items) and allowed herbs for functional foods (*) around the world
<table>
<thead>
<tr>
<th>項目</th>
<th>註說</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>註明著者的姓名和職務，以及在這份報告中的責任。</td>
</tr>
<tr>
<td>2.</td>
<td>提供有關資料的來源，包括期刊名稱、出版年份、頁碼和引用的頁碼。</td>
</tr>
<tr>
<td>3.</td>
<td>在報告中引用的所有資料都必須要有詳細的標誌，包括作者名稱、資料類型（文章、書籍、報告等）、出版年份、頁碼等。</td>
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Definition of health food in USA

Dietary Supplement:

Any product taken by mouth that contains a so-called “dietary ingredient” and its label clearly states that it is a dietary supplement. The dietary ingredients may include vitamins, minerals, herbs, and amino acids as well as substances such as enzymes, organ tissues, metabolites, extracts or concentrates.

Management of functional food

- statement of nutrition support “This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.”
**Structure/Function Claim**
Calcium builds strong bones.

**Health Claim**
Calcium may reduce the risk of osteoporosis.

**Drug Claim**
Calcium will prevent osteoporosis.

**Examples of Claims**

- **Health Claim**
  - Calcium may reduce the risk of osteoporosis.

- **Drug Claim**
  - Calcium will prevent osteoporosis.

- **Structure/Function Claim**
  - Calcium builds strong bones.
**Functional Food ?**

Food type, common use: including animal, plant and microbiological organism

**Nutraceuticals ?**

Powder, tablet or capsule (medicine like)

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**Definition of health food in Taiwan**

- Providing special nutrient or health benefit, claim or label on food. The purpose is not for disease therapy.
Toxicity and Function

- Safety evaluation pass first: microbial and animal systems
- Function evaluation:
  Animal system
  Human clinical
  Both animal and human design

Preclinical Trial: discovery

- Molecular structure
- Best combination
- …screening design, cluster analysis, discriminant analysis, factor analysis

- By animal:
  1. Dose-related response (regression)
  2. Pharmacological activity
Next step: **toxicology**

- Genetic toxicity
- Animal toxicity
- Reproductive toxicity
- Carcinogenic toxicity
- Dose-relationship (regression)

Further … **ADME**

- Absorption
- Distribution
- Metabolism
- Elimination

- Formulation (to the site of action) and *indicator compound(s)*
Formulation

- How to reach site of action: tablet, capsule, powder, liquid
- Lotion
- Cream
- Gel
- → Investigational New Drug Application, IND---For clinical trial
- indicator compound(s) is very critical for the quality control...

Clinical Trials

- Phase I
- Phase II
- Phase III
- Phase IV
Phase I

- Time to maximum concentration (T-max)
- Maximum concentration (Cmax)
- Area under the curve (AUC)
- Bioequivalence
- Bioavailability

- Subjects: 30~40y Health participants (n=20~80)

Phase II

- Subjects: patients
- Safety
- Efficiency
- Dose ranging
- Other pharmacological and pharmaco-kynetics
Phase III: adequate and well control

- Pivitol placebo-controlled study
- Active control study
- Further evaluation for the safety and efficiency
  - Short term (wks) and long term (1-2y)
  - Including elderly (>65y), or liver or kidney patients

After phase III

- New drug application (NDA)
- Commercialized
- Statistically valid
Phase IV

- After commercialized..
- Adverse event
- Pharmacological effect
- Elderly, child, pregnant
- Morbidity
- Mortality
- Indication (new purpose)

Experimental design (statistics)

- Identity
- Strength
- Quality
- Purity
Parallel and Cross-over

- **Ethics**: cross-over > parallel
- Cross-over: carry-over effect…washout period
- Cross-over: longer time (drop-out)
- Cross-over: phase I
- Parallel: phase II~IV
- Parallel are highly recommended

Single versus Multicenter trials

- Most by multicenter trials: easy to enroll subjects
- Single center: difficult enrolled (e.g. confection heart failure)
- Center effect: treatment-by-center interactions
Blinding and open-label

- Single blind: subjects don’t know, but researchers know that. *(based on ethics)*
- Double blind: subjects and operators don’t know, randomization schedule

- Always by *short-term double blind*, and then open-label

Randomized and Nonrandomized

- Most by randomized design
- *Completely randomized* design: subjects from all centers
- *Randomized block design*: subjects from each center
Placebo-controlled and active-controlled

- Phase II: placebo-controlled fewer placebo subjects than experiment
- Phase III: active-controlled (ethical), longer duration

- Evidence-based
- The new hope for medical treatment
- Scientific and stable significance

----- Challenge
Anti-aging Effect of *Ganoderma lucidum*:
A clinical trial
Growth of G. lucidum

1. 16 weeks after inoculation
2. Stem proliferation, 17 weeks
3. Mushroom cap proliferation, 18 weeks
Mushroom cap growth, 19 weeks

21 weeks

End of mushroom cap growth, 24 weeks

Harvesting

Ganoderma tsugae

Ganoderma formosanum
Highly used in Asian area for health promotion and diseases prevention.

Mild pharmacological effect

Classification: texture, color, and had been used as traditional herb

**Composition of *Ganoderma* fruiting body**

<table>
<thead>
<tr>
<th>Nutrient composition</th>
<th>Percentage</th>
<th>Nutrient composition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>54~56%</td>
<td>Polysaccharide</td>
<td>1.0~1.2%</td>
</tr>
<tr>
<td>Lignin</td>
<td>13~14%</td>
<td>Sterol</td>
<td>0.14~0.16%</td>
</tr>
<tr>
<td>Water</td>
<td>12~13%</td>
<td>Ash</td>
<td>0.022%</td>
</tr>
<tr>
<td>Monosaccharide</td>
<td>4.5~5.0%</td>
<td>Total phenol</td>
<td>0.08~0.12%</td>
</tr>
<tr>
<td>Fat</td>
<td>1.9~2.0%</td>
<td>Protein</td>
<td>0.08~0.12%</td>
</tr>
</tbody>
</table>
# Functional components

<table>
<thead>
<tr>
<th>Compounds</th>
<th>CHO</th>
<th>Triterpenoids</th>
<th>Protein</th>
<th>Uncleuic acid</th>
<th>Minerals</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Polysaccharide, Glucan</td>
<td>· Ganoderan</td>
<td>· Ganoderic acid</td>
<td>· Ling Zhi-8</td>
<td>· RNA, Adenosine</td>
<td>· Ge-132, K, Ca</td>
</tr>
<tr>
<td>· Ganoderan</td>
<td>· Lucidenic acid</td>
<td>· Lucidone</td>
<td>· Glycoprotein</td>
<td>· Adenine, Uracil</td>
<td>· P, Mg</td>
</tr>
</tbody>
</table>

## Triterpenoids

- Bitter taste source of *G. tsugae* and *G. lucidum*
- Liver protection
- Blood pressure regulation
- Suppression on cancer cells
- Inhibition on histamine release
- Anti-allergy
- Blood lipid down regulation
- Improvement on liver function

(Hitoshi et al., 1977; Kim et al., 1980; Miyazaki et al., 1981; Toth et al., 1983; Shimizu et al., 1985; Chen et al., 1997; Lai et al., 1997; Park et al., 1997)
Polysaccharides

- More than 200 polysaccharides have been isolated from *Ganoderma* species
- Linkage with protein moiety (polysaccharide peptide)
- Anticancer
- Immune promotion
- Antioxidation
- Promote the production of interleukin-1, –2 and IFN-γ

(Kino et al., 1989; Xia et al., 1989; van der Hem et al., 1995; Wang et al., 1997; Lai et al., 1997; Lin et al., 2000)
Antiaging and long life

Aging

- Age dependent
- Physiological activity
- Body function
- Cell death or damage
- Survival
Free radicals damage
Free radicals

Antioxidation and antiaging

ROS (reactive oxygen species), free radicals

VS diseases, aging

Antioxidation:
1. Oxidant indicator
2. Antioxidant enzymes

Organ indicator: liver function
Purpose

To evaluate the antiaging effect of *Ganoderma* extracts by human subjects by measuring the antioxidant status and liver function.

Anti-aging—animal model

Learning ability
Memory
Antioxidant status
Shelf life
**SAMP8 (Senescence accelerated mice)**

- Memory depression
- Short life: avg. 10 months
- Defect of learning and memory
- Suitable for aging study

**Aging:**

1. Reactivity
2. Skin glossiness
3. Periophthalmic lesion
4. Spine lordokyphosis
5. Retard on body weight
6. Hair loss
7. Contract
8. Beta amyloid protein
9. Poor immune

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**Active shuttle avoidance test**

- Stay in case for 10 sec.
- Light and sound stimulation in one side
- If no moving, electric shock every 5 seconds until to the other side
- 5 tests per time, four times every day, total 4 days
- Record the electric shock times
### Table Active shuttle avoidance test\(^1\,^2\)

<table>
<thead>
<tr>
<th>Group</th>
<th>Male</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>frequency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>14.13±0.53(^a)</td>
<td>10.80±0.34(^a)</td>
<td>9.20±0.46(^a)</td>
<td>7.27±0.44(^a)</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>8.93±0.41(^b)</td>
<td>6.40±0.51(^b)</td>
<td>4.53±0.31(^b)</td>
<td>2.80±0.31(^b)</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>8.60±0.32(^b)</td>
<td>5.07±0.33(^b)</td>
<td>4.28±0.34(^b)</td>
<td>2.27±0.32(^b)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>7.93±0.40(^b)</td>
<td>4.93±0.37(^b)</td>
<td>2.93±0.33(^b)</td>
<td>1.53±0.27(^b)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group</th>
<th>Female</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>frequency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>12.20±0.50(^a)</td>
<td>8.87±0.36(^a)</td>
<td>6.27±0.27(^a)</td>
<td>4.27±0.36(^a)</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>9.73±0.42(^b)</td>
<td>5.20±0.37(^b)</td>
<td>3.47±0.26(^b)</td>
<td>2.31±0.24(^b)</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>8.27±0.30(^b)</td>
<td>4.07±0.33(^b)</td>
<td>2.67±0.35(^b)</td>
<td>1.80±0.26(^b)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>6.80±0.30(^b)</td>
<td>3.60±0.45(^b)</td>
<td>2.27±0.28(^b)</td>
<td>1.53±0.24(^b)</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) Mean in the same column followed by different letters are significantly different (P < 0.05).

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### Single-trial passive avoidance test

- **stay at light space for 10 seconds**
- **electric shock when going into dark space for continuous 3 times**
- **24h, 48h, 72h, 7 day for test (no electric shock)**
- **record the time to stay in light space**
### Table Single trial passive avoidance test

<table>
<thead>
<tr>
<th>Group</th>
<th>Male trial</th>
<th>24 hr</th>
<th>48 hr</th>
<th>72 hr</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>time (sec)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>14.47±1.30a</td>
<td>29.40±2.45a</td>
<td>30.53±2.63a</td>
<td>16.67±1.30a</td>
<td>10.00±0.65a</td>
</tr>
<tr>
<td>A</td>
<td>16.47±1.94ab</td>
<td>40.80±2.63b</td>
<td>40.27±2.34b</td>
<td>29.53±2.04b</td>
<td>18.33±1.75b</td>
</tr>
<tr>
<td>B</td>
<td>15.73±1.59ab</td>
<td>49.67±3.73b</td>
<td>42.60±3.58b</td>
<td>27.73±2.64b</td>
<td>17.47±1.73b</td>
</tr>
<tr>
<td>C</td>
<td>19.80±1.01b</td>
<td>55.53±2.03b</td>
<td>47.80±1.93b</td>
<td>31.07±2.01b</td>
<td>20.00±1.27b</td>
</tr>
</tbody>
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<tr>
<td></td>
<td>time (sec)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Control</td>
<td>18.07±1.48a</td>
<td>32.07±1.99a</td>
<td>26.40±1.65a</td>
<td>15.13±1.21a</td>
<td>12.73±0.80a</td>
</tr>
<tr>
<td>A</td>
<td>17.27±1.38a</td>
<td>50.47±2.31b</td>
<td>47.47±2.19b</td>
<td>24.67±1.59b</td>
<td>18.60±1.28b</td>
</tr>
<tr>
<td>B</td>
<td>24.07±1.62b</td>
<td>54.67±2.10b</td>
<td>51.33±3.88b</td>
<td>34.67±2.45b</td>
<td>19.00±1.29b</td>
</tr>
<tr>
<td>C</td>
<td>25.33±2.79b</td>
<td>62.47±2.43b</td>
<td>55.20±2.83b</td>
<td>33.53±2.08b</td>
<td>19.67±1.13b</td>
</tr>
</tbody>
</table>

1 Values were mean ± S.E.M.

2 Mean in the same column followed by different letters are significantly different (P < 0.05)

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### Aging score (ranking from 0~4)

- **Behavior**
  - reactivity
  - passivity

- **Skin**
  - glossiness
  - coarseness
  - hair loss
  - ulcer

- **Eyes**
  - periophthalmic lesion

- **Spine**
  - spine lordokyphosis
### Table Aging score

<table>
<thead>
<tr>
<th>Group</th>
<th>Behavior</th>
<th>Male</th>
<th>Reactivity</th>
<th>Passivity</th>
<th>Glossiness</th>
<th>Coarseness</th>
<th>Hair loss</th>
<th>Ulcer</th>
<th>Eyes Periophthalmic lesion</th>
<th>Spine Lordokyphosis</th>
<th>Total</th>
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<td>1.33±0.13&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.20±0.14&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.53±0.13&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.40±0.13&lt;sup&gt;a&lt;/sup&gt;</td>
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<th>Passivity</th>
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<th>Ulcer</th>
<th>Eyes Periophthalmic lesion</th>
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<td>0.87±0.17</td>
<td>7.67±0.43&lt;sup&gt;a&lt;/sup&gt;</td>
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<td>0.93±0.15</td>
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<td>1.00±0.14</td>
<td>1.20±0.14</td>
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<td>0.73±0.15</td>
<td>7.13±0.35&lt;sup&gt;ab&lt;/sup&gt;</td>
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<tr>
<td>B</td>
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<td>6.13±0.42&lt;sup&gt;ab&lt;/sup&gt;</td>
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<td>5.40±0.31&lt;sup&gt;ab&lt;/sup&gt;</td>
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</tr>
</tbody>
</table>

Values were mean ±S.E.M.

2 Means in the same column followed by different letters are significantly different (P<0.05)

---

**Health Claims workshop by FIRN**

- **Sacrifice** (12 wk)
  - Biochem.
    - Total protein
    - Albumin
    - Triglyceride
    - Total cholesterol
    - HDL
    - LDL
  - Oxidation
    - Protein Carbonyl
    - TBARS
  - Enzyme
    - SOD
    - CAT
    - GSH-Px
  - Brain biopsy
    - β-amyloid protein deposition

**TBARS:** thiobarbituric acid reactive substances  
**SOD:** superoxide dismutase  
**CAT:** catalase  
**GSH-Px:** glutathione peroxidase
Hippocampus (HIP)

- Center for learning
- Accepting the sensory messages
- Long term memory formation
- Damage of HIP will lead to memory defects

**β-Amyloid deposition**

![β-Amyloid deposition images](image)

**Table β-amyloid deposition in the brain**

<table>
<thead>
<tr>
<th>Group</th>
<th>Male</th>
<th>Percentage of Aβ in brain (%)</th>
<th>Number of Aβ in brain (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>0.74±0.07&lt;sup&gt;a&lt;/sup&gt;</td>
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<td>24.60±5.54&lt;sup&gt;b&lt;/sup&gt;</td>
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</tr>
<tr>
<td>B</td>
<td>0.40±0.05&lt;sup&gt;c&lt;/sup&gt;</td>
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<tr>
<td>C</td>
<td>0.39±0.06&lt;sup&gt;c&lt;/sup&gt;</td>
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<table>
<thead>
<tr>
<th>Group</th>
<th>Female</th>
<th>Percentage of Aβ in brain (%)</th>
<th>Number of Aβ in brain (n)</th>
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<sup>1</sup>Values were mean ±S.E.M.<br><sup>2</sup>Mean in the same column followed by different letters are significantly different (P < 0.05)
Increasing antioxidant status

- Lower Malondialdehyde (MDA)
- Increasing total thiol groups
- Increasing activities of antioxidant enzymes in liver
  -- Catalase
  -- SOD
  -- G-6-PD

Shelf life
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<td>12/20</td>
<td>9/20</td>
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<td>(%)</td>
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<td>0</td>
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<td>20/20</td>
<td>19/20</td>
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<td>16/20</td>
<td>14/20</td>
<td>11/20</td>
<td>9/20</td>
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<tr>
<td>(%)</td>
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<td>5</td>
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<td>19/20</td>
<td>18/20</td>
<td>17/20</td>
<td>15/20</td>
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Human clinical trial
Study design

Double blind and crossover design

2.7 g Ganoderma extract/day (Double Crane Divine Ganoderma)

6.5% triterpenoids (ganoderic acid; 14.6mg/cap.)
6.0% polysaccharide peptide (13.5mg/cap.)
Table: Anthropometric measurements of subjects

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<tr>
<th></th>
<th>Group A Initial</th>
<th>Group A 3 months</th>
<th>Group A 6 months</th>
<th>Group B Initial</th>
<th>Group B 3 months</th>
<th>Group B 6 months</th>
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<tbody>
<tr>
<td>Age</td>
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<td>46.6±18.77</td>
<td>46.6±18.77</td>
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<td>44.74±17.07</td>
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<tr>
<td>Length(cm)</td>
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<td>165.93±9.24</td>
<td>165.93±9.24</td>
<td>164.53±7.93</td>
<td>164.53±7.93</td>
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<tr>
<td>Body wt.(kg)</td>
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<td>64.99±10.04</td>
<td>65.05±9.99</td>
<td>62.13±11.57</td>
<td>61.29±11.33</td>
<td>61.87±11.94</td>
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<tr>
<td>Body fat (%)</td>
<td>26.27±8.4</td>
<td>27.19±8.16</td>
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<td>25.79±8.82</td>
<td>26.05±8.95</td>
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<td>BMI(kg/m2)</td>
<td>23.63±2.6</td>
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<td>22.55±3.5</td>
<td>22.78±3.58</td>
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</tbody>
</table>

Values are means±SD.

Oxidant indicator (in plasma)

- Total antioxidant capacity
- TBARs
- Total thiols
- Glutathione
- 8-OH-dG
### Table 1. The total antioxidant capacity of plasma

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>(%)</td>
<td>80.70±5.04a</td>
<td>79.33±4.95b</td>
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<tr>
<td>Initial</td>
<td>80.97±3.98a</td>
<td>83.93±3.87a</td>
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<td>3 months</td>
<td>80.24±3.79a</td>
<td>84.04±3.74a</td>
</tr>
<tr>
<td>6 months</td>
<td>80.70±5.04a</td>
<td>80.24±3.79a</td>
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</table>

Values are means ±SD. Data within the same column sharing different superscript letters were significantly different (p < 0.05).

### Table 2. The contents of plasma TBARS

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Sample</th>
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</thead>
<tbody>
<tr>
<td>(μ mol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>3.26±0.09a</td>
<td>3.37±0.03a</td>
</tr>
<tr>
<td>3 months</td>
<td>3.32±0.73a</td>
<td>3.28±0.81a</td>
</tr>
<tr>
<td>6 months</td>
<td>3.30±0.88a</td>
<td>2.47±0.68b</td>
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</table>

Values are means ±SD. Data within the same column sharing different superscript letters were significantly different (p < 0.05).
### Table 3. The contents of total thiol groups in plasma

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<th></th>
<th>Placebo</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
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<td></td>
<td>(mM)</td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>0.21±0.08&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.19±0.06&lt;sup&gt;b&lt;/sup&gt;</td>
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<td>3 months</td>
<td>0.20±0.07&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.20±0.05&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>6 months</td>
<td>0.19±0.06&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.28±0.05&lt;sup&gt;a&lt;/sup&gt;</td>
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</table>

Values are means±SD. Data within the same column sharing different superscript letters were significantly different (p < 0.05).

### Table 4. The contents of plasma glutathione

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<th>Placebo</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>(μM)</td>
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</tr>
<tr>
<td>Initial</td>
<td>6.90±2.00&lt;sup&gt;a&lt;/sup&gt;</td>
<td>6.00±1.72&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>3 months</td>
<td>6.66±1.63&lt;sup&gt;a&lt;/sup&gt;</td>
<td>7.30±1.66&lt;sup&gt;a&lt;/sup&gt;</td>
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<tr>
<td>6 months</td>
<td>6.63±1.39&lt;sup&gt;a&lt;/sup&gt;</td>
<td>8.05±1.42&lt;sup&gt;a&lt;/sup&gt;</td>
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</table>

Values are means±SD. Data within the same column sharing different superscript letters were significantly different (p < 0.05).
Table 5. The contents of erythocyte 8-OH-dG

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</tr>
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<td></td>
<td>(pg/mL)</td>
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<tr>
<td>Initial</td>
<td>14.70±3.00a</td>
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<td>15.19±2.99a</td>
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<td>6 months</td>
<td>15.77±3.07a</td>
<td>11.98±1.79b</td>
</tr>
</tbody>
</table>

Values are means±SD
Data within the same column sharing different superscript letters were significantly different (p<0.05)

Antioxidant enzyme

- Super oxide dismutase (SOD)
- Glucose 6-phosphate dehydrogenase (G6PD)
- Catalase (CAT)
- Glutathione peroxidase (GSH Px)
- Glutathione reductase (GSH Rd)
Table 6. The activity of superoxide dismutase in erythrocytes

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>(IU/g Hb)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>1143.95±170.14a</td>
<td>1155.98±150.11c</td>
</tr>
<tr>
<td>3 months</td>
<td>1141.25±155.46a</td>
<td>1244.73±149.46b</td>
</tr>
<tr>
<td>6 months</td>
<td>1144.60±150.73a</td>
<td>1385.63±139.01a</td>
</tr>
</tbody>
</table>

Values are means±SD
Data within the same column sharing different superscript letters were significantly different (p < 0.05)
Table 7. The activity of glucose-6-phosphate dehydrogenase in erythrocytes

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(IU/g Hb)</td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>11.83±2.11&lt;sup&gt;a&lt;/sup&gt;</td>
<td>11.99±1.99&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>3 months</td>
<td>11.93±2.19&lt;sup&gt;a&lt;/sup&gt;</td>
<td>12.40±2.26&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>6 months</td>
<td>11.94±2.03&lt;sup&gt;a&lt;/sup&gt;</td>
<td>13.56±2.11&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Values are means±SD
Data within the same column sharing different superscript letters were significantly different (p<0.05)

Table 8. The activity of catalase in erythrocytes

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(kIU/g Hb)</td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>245.83±32.43&lt;sup&gt;a&lt;/sup&gt;</td>
<td>246.26±28.08&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>3 months</td>
<td>244.86±31.80&lt;sup&gt;a&lt;/sup&gt;</td>
<td>268.87±28.22&lt;sup&gt;ab&lt;/sup&gt;</td>
</tr>
<tr>
<td>6 months</td>
<td>242.97±28.32&lt;sup&gt;a&lt;/sup&gt;</td>
<td>279.21±26.18&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Values are means±SD
Data within the same column sharing different superscript letters were significantly different (p<0.05)
### Table 9. The activity of glutathione peroxidase in erythrocytes

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>(IU/g Hb)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>12.64±1.43&lt;sup&gt;a&lt;/sup&gt;</td>
<td>13.16±1.71&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>3 months</td>
<td>13.07±1.53&lt;sup&gt;a&lt;/sup&gt;</td>
<td>14.39±1.20&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>6 months</td>
<td>12.63±1.78&lt;sup&gt;a&lt;/sup&gt;</td>
<td>15.44±1.17&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Values are means±SD
Data within the same column sharing different superscript letters were significantly different (p < 0.05)

### Table 10. The activity of glutathione reductase in erythrocytes

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>(IU/g Hb)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>3.95±0.64&lt;sup&gt;a&lt;/sup&gt;</td>
<td>4.00±0.61&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>3 months</td>
<td>3.99±0.63&lt;sup&gt;a&lt;/sup&gt;</td>
<td>4.29±0.66&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>6 months</td>
<td>3.99±0.64&lt;sup&gt;a&lt;/sup&gt;</td>
<td>4.53±0.68&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Values are means±SD
Data within the same column sharing different superscript letters were significantly different (p < 0.05)
Clinical evaluation on liver

Abdominal ultrasonic exam.
GOT, GPT

Normal Liver, Fatty Liver, and Cirrhosis
Table 11. Biochemical analyses of serum GPT

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(U/L)</td>
<td>(U/L)</td>
</tr>
<tr>
<td>GPT Initial</td>
<td>20.05 ± 20.44a</td>
<td>22.58 ± 18.92a</td>
</tr>
<tr>
<td>3 months</td>
<td>20.25 ± 20.10a</td>
<td>16.85 ± 12.64b</td>
</tr>
<tr>
<td>6 months</td>
<td>21.33 ± 20.10a</td>
<td>13.08 ± 9.92c</td>
</tr>
</tbody>
</table>

Table 11. Biochemical analyses of serum GOT

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(U/L)</td>
<td>(U/L)</td>
</tr>
<tr>
<td>GOT Initial</td>
<td>19.65 ± 9.24a</td>
<td>20.65 ± 11.43a</td>
</tr>
<tr>
<td>3 months</td>
<td>20.45 ± 9.72a</td>
<td>19.85 ± 9.63a</td>
</tr>
<tr>
<td>6 months</td>
<td>19.90 ± 11.16a</td>
<td>15.05 ± 9.30b</td>
</tr>
</tbody>
</table>

Values are means ± SD
Data within the same column sharing different superscript letters were significantly different (p < 0.05)
Abdominal ultrasonic examination

Fatty liver (mild) → Normal
Conclusion

The above clinical evaluation clearly showed that:

- The total antioxidant status, total thiols and glutathione contents were significantly increased.
- TBARS and 8-OH-dG contents were reduced.
- Activities of GSH Px, SOD, G6PD and CAT were increased.
- Down regulation for subjects with higher GPT and GPT.
- Improvement on parenchyma liver disease and fatty liver.
Triterpenoids and polysaccharide peptides-enriched *Ganoderma lucidum*: a randomized, double-blind placebo-controlled crossover study of its antioxidation and hepatoprotective efficacy in healthy volunteers

Hsiuh-Fang Chiu¹, Hui-Yu Fu², Yan-Ying Lu³, Yi-Chun Han³, You-Cheng Shen³, Kamesh Venkatakrishnan⁴, Oksana Tsyshka⁵ and Chin-Kum Wang⁶

¹Department of Chinese Medicine, Taichung Hospital, Ministry of Health and Welfare, Taichung, Taiwan, Republic of China; ²School of Nutrition, Chung Shan Medical University, Taichung City, Taiwan, Republic of China; ³Department of Neurology, Chung Shan Medical University, Taichung City, Taiwan, Republic of China; ⁴School of Health, Diet and Industry Management, Chung Shan Medical University, Taichung City, Taiwan, Republic of China; ⁵Department of Food Science, ITMO University, Saint-Petersburg, Russia
Effect of Citronellol and the Chinese Medical Herb Complex on Cellular Immunity of Cancer Patients Receiving Chemotherapy/Radiotherapy

Shu-Ru Zhang1,2, Su-Lin Chen3, Jhi-Hsin Tsai4, Chi-Chou Huang5, Tsu-Chin Wu2, Wen-Shan Lin7, Hsien-Chun Tseng7, Hong-Sen Lee4, Min-Chung Huang6, Guang-Tzu Shane1, Cheng-Hua Yang6, You-Cheng Shen1, Yeong-Yu Yan7 and Chin-Kun Wang1

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British Journal of Nutrition (2012), 107, 72-738
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Effects of a Chinese medical herbs complex on cellular immunity and toxicity-related conditions of breast cancer patients


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(Received 25 August 2010 – Revised 24 May 2011 – Accepted 26 May 2011 – First published online 25 August 2011)
Improvement of Liver Function in Humans Using a Mixture of Schisandra Fruit Extract and Sesamin

Hui-Fang Chia,1 Izy-Yen Chen,2 Yu-Te Tzeng3 and Chin-Kun Wang4

1Department of Chinese Medicine, Taichung Hospital Department of Health, Taichung, Taiwan
2Department of Interior Medicine, Chung Shan Medical University Hospital, Taichung, Taiwan
3School of Nutrition, Chung Shan Medical University, Taichung, Taiwan

This was a randomized, parallel, and placebo-controlled study. Forty subjects were divided into a test group and a placebo group. The study was focused on the potential effects of a mixture of Schisandra fruit extract and sesamin (hereinafter called SCH) in the subjects with borderline high levels (40-60 U/L) of alanine aminotransferase (ALT) or aspartate aminotransferase (AST). Twenty subjects taking SCH (four tablets per day) and 20 subjects taking a placebo (four tablets per day) were studied. The effects of SCH on ALT, AST, total bilirubin, direct bilirubin, free radical levels, total antioxidant status, glutathione peroxidase, glutathione reductase, and the lag time for low-density lipoprotein oxidation were determined. The total test period was 5 months. Intervention of SCH clearly reduced the levels of ALT and AST, but it made no change in the total bilirubin and direct bilirubin. Intake of SCH also greatly increased the antioxidant capacity and decreased the values of thiobarbituric acid reactive glutathione, total free radicals, and superoxide anion radicals in the plasma. The activities of glutathione peroxidase and reductase in the erythrocytes were significantly increased. In addition, the lag time for low-density lipoprotein oxidation, an inflammatory marker, was evidently increased. Fatty liver was found to have been significantly improved in this study. SCH proved to have the effects of antioxidation and improving liver function. Copyright © 2012 John Wiley & Sons, Ltd.

Keywords: Schisandra fruit extract; sesamin; ALT; liver dysfunction; LDL oxidation.

Chung Shan Medical University (Medical Center)
Chung Shan Medical University

- CAM Center
- Clinical Trial Center
- IRB (Institute of Reviewing Board)
- Toxicity evaluation center
- R & D Center
- Incubation Center
256 slice CT

SIEMENS Somatom Sensation256

Positron Emission Tomography (PET)

A PET scan can be used in early diagnosis of cancer, helping physicians determine the best method for treatment.

CSMUH's Positron Emission Tomography Center: the largest in Southeast Asia
Cyclotron Center

Tomo Therapy
**Gamma Knife**

The Gamma Knife, a well-established treatment method, is not really a knife at all but a non-invasive treatment used for the brain problems.

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**Hyperbaric Oxygen Therapy Center**

**HBO Treatment Center**: The only managed by diving medicine faculty doctors in the middle of Taiwan
Laboratory Medicine

Research Team

- Zhu-Ching Wu, MD, Ph.D.
- Chi-Jo Hwang, MD, Ph.D.
- Tzy-Yen Chen, MD, Ph.D.
- Wen-Shan Liu, MD, Ph.D.
- Shen-Shin Zhin, MD, Ph.D.
- Su-Ru Zhuang, RD.
- Yu-Gin Lin, RD.
Research Team

Thanks for your attention