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# Salt reduction intervention: a cluster randomized trial in northern Thailand

**Submission date**
28/11/2011

**Recruitment status**
No longer recruiting

**Registration date**
03/01/2012

**Overall study status**
Completed

**Last Edited**
19/01/2021

**Condition category**
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**

Background and study aims:
Eating less salt can prevent cardiovascular diseases (CVD) such as heart attack and stroke. The World Health Organization has recommended the reduction of dietary salt as a CVD prevention strategy in developing countries where 80% of current global CVD deaths happen.
In order to make lifestyle changes including eating less salt, people have to first realize how high their daily salt intake is. We will support participants in the study group to be aware of their salt consumption. We will measure 24 hour salt intake by overnight urinary sodium measurement and the participants will know their actual daily salt intake. We will then ask the participants to bring their food to the health center. The salt content of food will be measured and shown to the participants. They will be aware of the salt content of their food, and start voluntarily changing their dietary pattern. Such life style changes will decrease CVD events on long term. We will test this hypothesis by providing a special health education program which makes people realize the actual daily salt intake and salt content of daily meals.

Aims:
To compare the effectiveness of health education program making participants realize the actual daily salt intake versus routine health education in high cardiovascular risk patients.
The following will be measured between the two study groups:
1. Behaviour change
2. Blood pressure
3. Incidence of cardiovascular disease
To compare the cost-effectiveness of health education of actual daily salt intake versus routine health education in high cardiovascular risk patients.

Who can participate?
Both men and women, above age of 35 years can participate in the study.
The participants are patients attending to the diabetes and hypertension clinic at the community hospitals and they are having higher CVD risk. We will use "the general Framingham scoring for CVD risks" to screen high risk CVD patients.

What does the study involve?
Study group participants will be informed of the salt content in their usual meals by measuring

salt content using a food salt metre 5 times a year at health centre. They will also be informed of how much salt they have eaten in the last 24 hours, which is measured using an overnight urinary sodium measurement, once a month. They will also receive dietary advice to reduce the salt consumption based on their salt intake. They will receive group education by a nutritionist and individual counselling by a nurse.
The other group will receive the health education routinely given by the health centres and participants will be asked for overnight urine samples to measure salt intake in the last 24 hours, once a month. The health centre staff will give advice based on your salt intake but participants will receive the results at the end of one year.

What are the possible benefits and risks of participating?
Participants in both groups will know the 24 hour salt consumption by overnight urinary sodium measurement. The study will not introduce any particular risk to participants.

Where is the study run from?
We will run the study at eight health centres in Muang district, Chiang rai province, Northern Thailand. The Primary Care Unit at the Chiang rai provincial hospital is the leading centre.

When is study starting and how long is it expected to run for?
The trial will recruit participants for two months from December 2011 and the study will end in 2013.

Who is funding the study?
Department of Public Health, Graduate School of Medicine, Juntendo University, Japan - Ministry of Education, Culture, Sports, Science and Technology Grant ref: 22256002

Who is the main contact?
Associate Professor Motoyuki Yuasa
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
11/2011

# Study information

### Scientific Title
REducing Salt Intake for Prevention of CardioVascular Disease in high risk patients: a cluster randomized trial of advanced health education intervention in northern Thailand (RESIP-CVD study)

### Acronym
RESIP-CVD

### Study objectives
Health education together with visualization of the salt content in daily food and the individual daily salt intake will have greater effect than routine health education to change the lifestyle of eating a high salt diet.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Juntendo University, Japan, 1 July 2011, ref: 2011036
Chiang Rai Regional Hospital, Thailand, 17 November 2011, ref: CR0027.102/research/207

### Study design
Cluster randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Cadiovascular disease

### Interventions
Health Education intervention:
1. Special Health Education class by dietician
2. Visualization of salt content in sample of patients food/soup
3. Explanation of dangers of high salt diet leading to cardiovascular death

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
1. Blood pressure
2. Omron Digital BP monitor HEM 907

### Secondary outcome measures
1. Behaviour change: salt intake estimated by urine sodium using KME-03
2. Clinical outcome: cardiovascular disease (CVD) risk measured using the General Framingham Score (10 year risk)
3. CVD incidence: diagnosis of each CVD event
4. Surrogate outcome: retinal caliber

### Overall study start date
20/12/2011

### Completion date
20/12/2013

## Eligibility

### Key inclusion criteria
1. Diabetic patients with high risk of cardiovascular risk by General Framingham scoring 10 years risk (>15%)
2. Hypertensive patients with high risk of cardiovascular risk by Framingham scoring (>15%)
3. Patient who are willing to participate in the study

### Participant type(s)
Patient

### Age group
Adult

### Sex

Both

### Target number of participants
800

### Total final enrolment
753

### Key exclusion criteria
1. Any female patients who are pregnant
2. Patients aged younger than 35 years
3. Patients with documented type I diabetes
4. Those on long term steroid therapy (more than 2 weeks)
5. Those on long term non-steroidal anti-inflammatory drugs (NSAIDs) (i.e. every day for at least one year)
6. Patients with cancer
7. Patients with known secondary hypertension such as primary aldosteronism, cushing disease syndrome or Pheochromocytoma
8. Patients with severe chronic pulmonary diseases using home oxygen therapy
9. Patients with chronic renal disease (Creatinine2.0 mg/dl)
10. Patients with Congestive Heart Failure

### Date of first enrolment
20/12/2011

### Date of final enrolment
20/12/2013

## Locations

### Countries of recruitment
Japan

Thailand

### Study participating centre
### Department of Public Health
Tokyo
Japan
113-8421

## Sponsor information

### Organisation
Ministry of Education, Culture, Sports, Science and Technology (Japan)

### Sponsor details
Kasumigaseki 3-2-2
Chiyoda-ku
Tokyo
Japan
100-8959

### Sponsor type
Government

### Website
http://www.mext.go.jp/english/

### ROR
https://ror.org/048rj2z13

## Funder(s)

### Funder type
Government

### Funder Name
Ministry of Education, Culture, Sports, Science and Technology (Japan)

### Alternative Name(s)
Monbu-kagaku-shō, , MEXT

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
Japan

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 04/09/2012 | | Yes | No |
| Results article | results | 22/09/2020 | 19/01/2021 | Yes | No |