

## Trial Description

### Title

**Environmental and educational intervention in communal catering to lower salt intake in the Swiss working population**

### Trial Acronym

**Gesund+Gut: Na Klar!**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Background:** High salt intake is a risk factor for cardiovascular disease. The Swiss salt strategy therefore seeks to gradually reduce salt intake to the international recommendation of five grams per day. The investigation looks at the impact of various measures to reduce salt intake among test participants who regularly take their meals at staff restaurants.

**Aim:** Many workers regularly take lunch at a company-provided staff restaurant. This study investigates how salt intake and the associated blood pressure of the working population can be reduced by means of measures in relation to promoting health within the workplace. This is done by gradually optimising the salt content in the food offered by the staff restaurants of voluntarily participating companies over the course of one year. During the same period, the kitchen staff and staff restaurant users are given theoretical information and practical advice on health eating. The purpose of these measures is to motivate the participants in the study and support them in gradually improving their skills, attitudes, and habits in relation to food preparation and consumption. The salt content of the meals offered is investigated in the laboratory. The salt intake, blood pressure, weight, size and health awareness of study participants are also assessed. Finally, the results are compared with those collected from companies that have not changed their staff restaurant offering.

**Significance:** The project is delivering new findings on the factors that encourage or prevent the implementation of health promotion measures in companies and staff restaurants. It will show the extent to which general health can be promoted at low cost. The findings will allow measures intended to reduce salt intake to be assessed in relation to their practical relevance and transferability. This will allow for feasible catering and training plans to be created, and other activities to promote healthy living to be developed at policy, corporate and individual levels.

### Brief Summary in Scientific Language

Reducing salt intake at the population level is considered a promising and cost-effective means to reduce cardiovascular disease risk. The Swiss Salt Strategy is pursuing an average salt intake of <8g per person per day at the population level (a 16% reduction) as intermediate goal. For the longer term, the aim is to decrease the intake to 5g/day, as recommended by WHO. Measures should

**address the overall salt intake distribution in the typical Swiss diet focusing on a stepwise reduction of salt content in major food sources, including offers by the food service industry, and taking into account consumers health literacy and related behaviours.**

**A one year, four-phased community trial is planned in organizations/staff canteens in German-speaking Switzerland, with an intervention and a control group (up to 400 consumers each, 15-65 yrs old from matching canteens; 2x8 clusters,). The objective is to demonstrate the effectiveness of a combined progressive environmental and nutrition educational/motivational intervention in the workplace in reducing the consumers average daily total dietary salt intakes by 16% or more (according to the Swiss salt strategy intermediate goal). For the intervention group the luncheons' salt contents are reduced step by step, i.e. 4% per phase (total 4x4% = 16% reduction) and concurrently study participants are provided with increasingly specific information (knowledge and skills) on how to put a nutritionally well-balanced diet into action. The consumers in the control group are being served habitual luncheons and they have access to publicly available, general information on healthy eating only. Outcome measures are changes in sodium/salt intake (24 hour and spot urine collection), blood pressure, overall diet composition (3 day food record checklist), anthropometric indices (weight, height, waist and hip circumference) and health literacy (health literacy questionnaire) in the intervention as compared with the control group. Measures are taken at 0/3/6/9/12 months and 0/6/12 months for the intervention and control group, respectively.**

**The community trial will help identifying barriers and promoters for participation of organizations, their staff canteens and their employees. It will demonstrate the practical relevance, and in consequence, the exportability of the shown effectiveness of the intervention elements. The research results should be incorporated in the establishment of easily applicable concepts which facilitate manufacturing/providing and consuming a healthy diet for a healthy life.**

**Note: The intended cluster (organization) randomization proved infeasible.**

**Organizations interested in participation did not accept random allocation to arm 1 (intervention) or arm 2 (control).**

## Organizational Data

- DRKS-ID: **DRKS00006790**
- Date of Registration in DRKS: **2014/09/23**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **130/14 , Kantonale Ethikkommission Bern (KEK)**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **I10.9 - [generalization I10: Essential (primary) hypertension]**
- Free text: **High salt intake (lifestyle risk factor)**

## Interventions/Observational Groups

- Arm 1: **Up to 8 intervention organizations/staff restaurants are compared with control organizations (clusters), with up to 50 participants each. Assisted salt reduction program (4x4%, food analysis) of nutritional adequate food supply, implementing Swiss quality standards for health-promoting communal catering. Education program, providing participants with progressively specific information on how to put a health-promoting salt-reduced tasty diet in action. Salt intake (24h/spot urine), blood pressure, anthropometrics, health literacy measured at 0/3/6/9/12 months.**
- Arm 2: **Control: no change to food supply (food analysis) and no education program (measures at 0/6/12 months)**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Sodium (Na)/salt intake; Method of measurement: 24 hour a/o spot urine Na excretion; Timepoints: Baseline, 3, 6, 9 and 12 months**

## Secondary Outcome

**Overall qualitative diet composition (Na/K ratio); Blood Pressure; Anthropometrics (weight, height; waist and hip circumferences); Health/Food literacy**

## Countries of recruitment

- CH **Switzerland**



## Locations of Recruitment

- other **Unternehmen mit Personalrestaurant, Kantone BE, AG, SO, BL, BS, LU, ZG und ZH**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/03/23**
- Target Sample Size: **800**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **15 Years**
- Maximum Age: **65 Years**

## Additional Inclusion Criteria

**15-65 years old employees of organizations with staff restaurant; eating at least 2 times/week in staff restaurant; available for 5 education sessions during 12 months; sufficiently literate in German to read/complete forms/questionnaires and follow education program.**

## Exclusion criteria

**Medical or non-medical indication and/or medication that interfer with urine collection/analyses; Women being pregnant at time of recruitment; severe food allergy, intolerance or aversion hampering staff restaurant use.**

## Addresses

### ■ Primary Sponsor

**Institut für Sozial- und Präventivmedizin, Universität Bern  
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URL: **www.gesundheit.bfh.ch**

## **Sources of Monetary or Material Support**

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**Schweizerischer Nationalfonds  
Wildhainweg 3  
3001 Bern  
Switzerland**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: **www.snf.ch**

- **Private sponsorship (foundations, study societies, etc.)**

**Schweizerische Herzstiftung  
Schwarztorstrasse 18, Postfach 368  
3000 Bern 14  
Switzerland**

Telephone: **41 31 388 80 82**

Fax: [---]\*

E-mail: **info at swissheart.ch**

URL: **http://www.swissheart.ch**

## **Status**

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/11/04**

## **Trial Publications, Results and other documents**

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- Further trial documents **The intervention manuals and materials, and the used questionnaires are accessible via the Bern Open Repository and Information System (BORIS, University of Bern)**
  - Paper **All publications are made accessible via the Bern Open Repository and Information System (BORIS, University of Bern)**

*\* This entry means the parameter is not applicable or has not been set.*

*\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.*