Determining Sample Size
considerations for intervention studies & surveys

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Introduction Sample Sizes

• Why is it important to consider the required sample size for a study?
Introduction Sample Sizes

- Why is it important to consider the required sample size for a study?

Objectives of this lecture

- Understanding of the principles of sample sizes in terms of evaluating complex interventions
- Understanding of different methods of calculating sample sizes appropriate for evaluating complex interventions
- Understanding the contribution of clusters in calculating sample sizes
What are important concepts to know

- Research population
- A sample
- Sample scheme
- Design

**Research problem** ➔ **Research question** ➔ **Methodology**

Importance of good sample sizes

- Representativeness: does your sample represent the population?
- Selection bias: over / under representing of some subgroups
- Generalisation: can you generalise the results of the sample to the population?

**Populations & Samples**
The focus is on a population though we can only examine samples
Sample size methods

1. Probability sampling – a select / a random sample

2. Non-probability sampling – select / a non random sample

Sample size: 1. probability sampling

When?
• List of the whole population
• Generalisation is important
• Often quantitative studies

A population

A sample
Sample size: 1. probability sampling

1. A simple random sampling
2. Stratified random sampling
3. Cluster random sampling
4. Systematic random sampling

• All people in the population have the same chance to be selected
• For example:
  • Patients
  • Students

Sample size: 1. probability sampling

2 Stratified random sampling

- Populations divided into subpopulations: strata
  - For example: social economic status / school

<table>
<thead>
<tr>
<th>Gestrificeerde steekproef</th>
<th>Method of sampling</th>
<th>Resultante steekproef</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>Method of sampling</td>
<td>Resultante steekproef</td>
</tr>
<tr>
<td>De populatie wordt (bijvoorbeeld) ingedeeld in twee subgroepen (strata)</td>
<td>Een aselecte keuze van een proportioneel aantal stratumleden uit elk stratum</td>
<td>Elk lid van elk stratum (I of II) in de populatie heeft een gelijke kans om in de steekproef te worden opgenomen (proportioneel steekproef)</td>
</tr>
</tbody>
</table>


Sample size: 1. probability sampling

3 cluster random sampling

- Populations devided into subpopulations: strata
  - For example: social economic status / school

Center for statistics University of Hasselt, Belgium
Sample size: 1. probability sampling

- Whole populations

Summary: 1. probability sampling

- Generalize to the population
- Less change of selection bias, but no guaranty
- Less practical – Costly & time consuming
Sample size: 2. non probability sampling

When?
• Generalisation to the whole population is not important
• Not enough resources: money, time
• Tracing the population is difficult???

• Used for quantitative & qualitative studies

1. Convenience sampling
2. Snowball sampling
3. Quota sampling
4. Purposeful sampling
Sample size: 2. non probability sampling

Convenience sampling

• Also called accidental sampling
  • Survey among students of a university you work with
  • Survey among nursing of a hospital you know
  • Survey among people who are in one shopping area

Sample size: 2. non probability sampling

Snowball sampling

• Also called chain sampling
Sample size: 2. non probability sampling

**Quota sampling**

- A convenience sampling within a strata
- Strata is defined by data of the population
  - Gender
  - Education level
  - Medical disease

**Strata**

**Convenience sampling**

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**Sample size: 2. non probability sampling**

**Quota sampling**

<table>
<thead>
<tr>
<th>Strata</th>
<th>Population</th>
<th>Convenience sampling</th>
<th>Quota sampling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>100 (20%)</td>
<td>5 (5%)</td>
<td>20 (20%)</td>
</tr>
<tr>
<td>Women</td>
<td>400 (80%)</td>
<td>95 (95%)</td>
<td>80 (80%)</td>
</tr>
<tr>
<td>Total</td>
<td>500 (100%)</td>
<td>100 (100%)</td>
<td>100 (100%)</td>
</tr>
</tbody>
</table>
Sample size: 2. non probability sampling

Purposeful sampling

- When:
- Select specific people in your study
- For example testing a new intervention

Summary: 2. non probability sampling

- Are practical
- Be aware of selection bias
- Compare the sample with the population
Calculating sample sizes

Why?

Because:
- The focus is often on a population though typically we can only examine samples
- The task of statistics is to:
  - Estimate the properties of a population from those of the sample
  - Estimate the effect of an intervention in a population from the effect in a sample

Talk with your statistician about calculating the sample size
Calculating sample sizes

Factors that influence the power of a study
• Desired power level – Errors in testing hypothesis: Type I / II
• Estimated effect size
• Design of the study
• Measurement level
• The outcome
• Analysis techniques

Decision based on statistical test

<table>
<thead>
<tr>
<th>Unknown if hypothesis is true</th>
<th>No treatment effect</th>
<th>Treatment effect exists</th>
</tr>
</thead>
<tbody>
<tr>
<td>No treatment effect</td>
<td><strong>Correct decision</strong></td>
<td><strong>Type I error</strong></td>
</tr>
<tr>
<td>Treatment effect exists</td>
<td>$p = 1 - \alpha$</td>
<td>$p = \alpha$</td>
</tr>
</tbody>
</table>

Power

Correctly reject a false hypothesis

$\alpha$ = Type I error
$\beta$ = Type II error
$\text{Power} = 1 - \beta$
Example: Washing Without Water study

Cost-consequence analysis of “washing without water” for nursing home residents: A cluster randomized trial
Lisette Schoenmakers, G.J. van Gaal, B. Wens, L. Tenenbaum, Eddy Adang, Carine van der Vleuten, Theo van Achterberg

Aims
• To compare skin damage
• To compare costs

Intervention
Washing with disposable Washing gloves

Control
Traditional Bathing

Work in groups

Read the summary of the Washing Without Water study and answer the next questions with your group.
1. What sample size methods has been used in that study?
2. What information do you need to calculate the sample size before the start of this study?
Work in groups

1. Sample size method:

2. Needed information to calculate the sample size:

Sample size & the MRC framework

- Feasibility and piloting
  - Testing procedures
  - Estimating recruitment and retention
  - Determining sample size

- Development
  - Identifying the evidence base
  - Identifying or developing theory
  - Modelling process and outcomes

- Evaluation
  - Assessing effectiveness
  - Understanding change process
  - Assessing cost effectiveness

- Implementation
  - Dissemination
  - Surveillance and monitoring
  - Long term follow-up

(Craig P et al. 2008)
Sample size & the MRC frame work

- Identify the important effect – the outcome – and how to measures
- Making plausible estimate of likely effect
- Identifying existing studies from which estimates of likely effect and sampling variability can be drawn
- Estimating the prevalence of a problem
  - Finding study subjects
  - Impact / return on investment

Sample size & the MRC frame work

- Insufficient prior information to calculate sample size required...
- Gathering data about variability in instruments etc. for definitive evaluation:
  - Assessing feasibility of recruitment and dropouts that will effect sample size
  - Estimates of variability (SD) of the population
  - Identifying baseline rates
- Testing study procedures
Sample size & the MRC frame work

Definitive evaluation

- Power calculation required in advance for definitive study
- Must define main endpoint and the precision required (smallest effect that is important):
- ‘Post hoc’ power calculations (what the power was, after the study) are meaningless

Some specific considerations

- Cluster (randomised) studies
  - Standard techniques do not take into account correlations between individuals within clusters
  - Larger samples are required
- Cost effectiveness
  - Variation occurs on 2 parameters: cost and effect
  - Effect on sample size varies depending on the strength and direction of the correlation
Summary – determining sample size

• In this lecture showed the
• Different methods to sample your study population from the populations
• The importance of a proper sample size calculation
• The importance to meet your statistician and decide what the best sample size is for your study as
  • Onw size does noet fit all, afbeelding
Washing Without Water – study

Read the summary of this study and answer the next questions:

1. What sample size methods had been used in this study?
2. What information do you need to calculate the sample size before the start of this study?

**Background:** No-rinse disposable wash gloves are increasingly implemented in health care to replace traditional soap and water bed baths without proper evaluation of (cost) effectiveness.

**Objectives:** To compare bed baths for effects on skin integrity and resistance against bathing and costs.

**Design:** Cluster randomized trial. Randomization was performed prior to baseline data collection and at the level of nursing home wards. Residents within the same ward were considered to be a cluster

**Setting & Participants:** Five hundred adult care-dependent residents from nursing home wards.

**Methods:** The experimental condition ‘washing without water’ consists of a bed bath with disposable wash gloves made of non-woven waffled fibers, saturated with a no-rinse, quickly vaporizing skin cleaning and caring lotion. The control condition is a traditional bed bath using soap, water, washcloths and towels. Both conditions were continued for 6 weeks.

**The primary outcome** for this study was prevalence of skin damage, defined as clinical symptoms of intertrigo, (contact) dermatitis, or candidiasis. We distinguished two levels of severity of skin damage: any skin abnormality/lesion and significant skin lesions: 1) Any skin abnormalities/lesions were considered present when at least one of the following symptoms were observed: bright red discoloration; erythema; white, green or yellow discoloration of the woundbed; atrophic and shiny skin; satellite lesions and kissing lesions, fissures, erosions or ulcerations. These symptoms should be present on the buttocks or one of the following 10 skin folds: eyes, neck, armpits, elbows, sub-mammary region, umbilicus, abdomen, groins, anal cleft, and between toes. 2) Significant skin lesions were considered present if the skin was not intact on the buttocks or one of the following four skin folds: sub-mammary region, abdomen, groins, and anal cleft.

**Additional outcomes:** resistance during bed baths, costs.

**Results:** Any skin abnormalities/lesions over time decreased slightly in the experimental group, and increased slightly in the control group, resulting in 72.7% vs 77.6% of residents having any skin abnormalities/lesions after 6 weeks, respectively (p = 0.04). There were no differences in significant skin lesions or resistance after 6 weeks.