# STATISTICAL ANALYSIS PLAN - CARDIOVASCULAR RISK EXPERIMENT

Study:          Actively Choosing How to Cope with an Increased Risk of Cardiovascular Disease: A Randomised Web-Based Experiment
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ClinicalTrials: NCT05142280
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Data:           M:\projecten\2017\PowerToThePeople\Lab experimenten\Online experiment 2\Databestanden

## RESEARCH QUESTION

What is the differential impact on psychological outcomes between promoting an active and a passive choice process regarding lifestyle changes and medication use to reduce cardiovascular risk?

## HYPOTHESIS

Promoting an active choice regarding lifestyle changes and medication use to reduce cardiovascular risk has a different impact on psychological outcomes compared to promoting a passive choice.

## DESIGN

Online randomized controlled trial with two conditions: active choice condition (intervention) versus passive choice condition (control).

## STEPS IN DATA PREPARATION, CLEANING, CODING AND ANALYSIS

### Preparation, cleaning, editing, coding

- Rename variables; this will make interpretation of the variables easier. We will do this using syntax.
- Selection of participants that meet the inclusion criteria.
- Recode variables that need to be recoded.
    - If participants intend to change their lifestyle and take medication, they will be asked more questions (i.e. for lifestyle and medication separately). For these participants, we will use the highest score on the items (and not the average).
    - For the 4 knowledge items, we will merge the 'wrong answer' with the option 'Don't know'.
    - We will dichotomize the control preferences scale (5-point scale) for the analysis of effect modification. As a research team, we decided that we will consider scores 1-2 as 'active preference' and scores 4 and 5 as 'passive' preference. Score 3 (preference for shared decision making) will not be used in the analysis.

- Check frequencies and descriptives to check for missing data and distributions.
  *Missing data will be indicated as 'system missing' by the research agency. We will exclude missing values pairwise in the analyses.*

- Construct scales/composite scores: we will create composite scores for items that belong together and that show reasonable internal consistency (i.e., a Cronbachs alpha of .70 or higher). Composite scores will be calculated by adding op the score on the items an dividing them by the number of items.
  - ❖ The Treatment Self-regulation Questionnaire website (Treatment Self-Regulation Questionnaire – selfdeterminationtheory.org) says: "Each participant gets a score on each subscale by averaging responses to each of the items that make up that subscale." Since we only include the 'Autonomous Motivation' subscale, we will average the items of this subscale.

## Statistical analyses

- Before conducting the regression analyses, we will check whether the assumptions have been met:
- Assumptions for linear regression analysis:
  - o Dependent variable has a normal distribution
  - o Linear relation between independent and dependent variable
  - o Also: https://www.statisticssolutions.com/assumptions-of-linear-regression/
- Assumptions logistic regression analysis:
  - o https://www.statisticssolutions.com/assumptions-of-logistic-regression/
- Moreover, we will investigate:
  - o Confounding by Age on the 3 primary outcome measures (i.e., degree of active choice, intention strength and commitment). If confounding is found, we will also check whether it applies to the secondary outcome measures, and we will correct for age in the main analyses.
  - o Effect modification by gender, educational level (3 levels), health condition (yes/no), and decision making preferences (active/passive) on the 3 primary outcome measures (i.e., degree of active choice, intention strength and commitment). If effect modification is found, we will also check whether it applies to the secondary outcome measures.

- ❖ **Analyses:**

  - o **Active Choice**
    Linear regression analysis with condition as independent variable and Degree of Active Choice as dependent variable.

  - o **Intention strength**
    Linear regression analyses with condition as independent variable and Intention strength as dependent variable.

- o **Commitment**

  Linear regression analysis with condition as independent variable and Degree of commitment as dependent variable.

- o **Intention**

  Multinomial logistic regression analysis with condition as independent variable and Intention as dependent variable.

- o **Lifestyle Intention: diet**

  Logistic regression analysis with condition as independent variable and intention to change diet as dependent variable.

- o **Lifestyle Intention: physical activity**

  Logistic regression analysis with condition as independent variable and intention to change physical activity as dependent variable.

- o **Self-efficacy**

  Linear regression analysis with condition as independent variable and Self-efficacy as dependent variable.

- o **Response efficacy: lifestyle**

  Linear regression analysis with condition as independent variable and Response efficacy as dependent variable.

- o **Response efficacy: medication**

  Linear regression analysis with condition as independent variable and Response efficacy as dependent variable.

- o **Autonomous Motivation**

  Linear regression analysis with condition as independent variable and Autonomous motivation as dependent variable.

- o **Knowledge**

  Ordinal regression analysis with condition as independent variable and number of correct answers as outcome variable.

- o **Cognitive risk appraisal**

  Linear regression analysis with condition as independent variable and Cognitive risk perception as dependent variable.

- o **Affective risk appraisal (negative affect)**

  Linear regression analysis with condition as independent variable and Affective risk appraisal as dependent variable.