

CLINICAL TRIAL OUTLINE APPLICATION

1. STUDY SYNOPSIS

APPLICANT / COORDINATING INVESTIGATOR	Vorlesung Biometrie im Querschnittsbereich MSE_P_304, 3. Studienjahr, Terial CAB, Übungsgruppe 1 Medizinische Hochschule Hannover Carl-Neuberg-Str. 1, 30625 Hannover
TITLE OF STUDY	Investigation of the effect of watching Youtube videos on vital signs - a randomized trial in healthy volunteers
CONDITION	Healthy volunteers, members of Übungsgruppe 1
OBJECTIVE(S)	Effects of videos on vital signs (pulse, blood pressure) are investigated. Thrilling video content is compared in the experimental arm to calm content in the control arm. It is hypothesized that the experimental arm leads to an increase.
INTERVENTIONS(S)	<u>Experimental intervention:</u> Participants watch a video with exciting/thrilling content. Vital signs are measured. <u>Control intervention:</u> Participants watch a video with calm/placid content. Vital signs are measured. <u>Follow-up per patient:</u> max. 4 min <u>Duration of intervention per patient:</u> max. 4 min
KEY INCLUSION AND EXCLUSION CRITERIA	<u>Key inclusion criteria:</u> <ul style="list-style-type: none"> • Übungsgruppe 1 • Ability and willingness to participate • Informed consent <u>Key exclusion criteria:</u> <ul style="list-style-type: none"> • NYHA III or IV
OUTCOME(S)	<u>Primary efficacy endpoint:</u> Change of pulse rate [bpm] defined as difference between maximum pulse rate during intervention and pulse rate before intervention (Change = Max – Baseline). <u>Key secondary endpoints(s):</u> change of systolic blood pressure [mmHg] defined as difference between pre- and post-intervention measurements (Change = Post - Baseline)
STUDY TYPE	prospective, randomized, parallel group, monocenter, controlled clinical trial
STATISTICAL ANALYSIS	<u>Description of the primary efficacy analysis and population:</u> Change of pulse rate is compared between the two treatment groups with a two-sided t-test for independent samples at a significance level of 5%. A two-sided 95% confidence interval will be provided for the mean difference between treatment groups. Primary analysis will be in the Intention-to-treat population. <u>Secondary endpoints:</u> Change of systolic blood pressure is compared between the two treatment groups with a two-sided t-test for independent samples at a significance level of 5%. A two-sided 95% confidence interval will be provided for the mean difference between treatment groups.
SAMPLE SIZE	<u>To be assessed for eligibility:</u> (n = 29) <u>To be allocated to trial:</u> (n = 20) <u>To be analysed:</u> (n = 20)
TRIAL DURATION	<u>Time for preparation of the trial (months):</u> 5 days <u>First patient in to last patient out (months):</u> 1 day <u>Duration of the entire trial (months):</u> 2 days <u>Recruitment period (months):</u> 1 day
PARTICIPATING CENTRES	n = 1 (MHH)
PREVIOUS BMBF/DFG PROJECT NUMBER	