

Preregistration on Clinicaltrials.gov

Project:

„Hypnosis Induction and Height Experience in VR - Control Group Comparison and Three Sessions“

Unique Protocol ID: 521/2019BO2

Description of the Hypotheses, Analyses and needed Sample Sizes

06.05.2024

1. Data collection. Have any data been collected for this study already?

No data has been collected for this study.

2. Hypothesis: What's the main question being asked or hypothesis being tested in this study?

- a. Do three sessions of VR therapy reduce the fear of heights in both groups?
 - i. We expect a decrease in fear of heights over the sessions.
 - ii. Fear of heights decreases over the three sessions, with the experimental group benefiting more from the sessions than the control group.
- b. The fear of heights increases less from after the last therapy session to the follow-up measurement after one week in the experimental group than in the control group.
- c. Does the anxiety experience curve change during the VR height confrontation over the three sessions in both groups?
 - i. We expect typical anxiety experience curves according to the habituation (linear increase in anxiety and quadratic decrease).
 - ii. We expect a decrease of the mean anxiety experience rating over the sessions.
 - iii. We expect that the anxiety experience curves rise less sharply with each session.
 - iv. We expect that the anxiety experience curves reach their turning point earlier with each session.
 - v. The experimental group has lower anxiety experience ratings across all sessions and rises (20 ascents during the height confrontation) compared to the control group.
- d. How does a person's suggestibility influence the perception and impact of the intervention?
 - i. More suggestible people show a greater reduction in anxiety over the three sessions than less suggestible people.
 - ii. The influence of suggestibility on the strength of reduction in anxiety over the three sessions is stronger in the experimental group than in the control group.
 - iii. Suggestibility and group affinity interact such that in the experimental group participants with higher suggestibility show a lower level of anxiety experience during the height confrontation than less suggestible participants, but in the control group higher suggestible participants exhibit greater anxiety experience during the height confrontation than less suggestible participants.

3. Analyses

The analyses are carried out using linear mixed models. Each model is tested with the car::Anova() function (model comparison Typ II ANOVA) in R to determine the significance of the individual effects. The model equations are written down below and the abbreviations used for the effects are explained.

grp: experimental vs. control group (enters model equation as factor: experimental

group is reference group)

sugg: suggestibility (enters model equation as linear predictor)

a. HIQ ~ grp + sess + grp:sess + (1 | id)

sess: baseline vs. post first session vs. post second session vs. post third session (enters model equation as factor)

For hypothesis a(i) we investigate the significance of sess.

For hypothesis a(ii) we investigate the significance of grp:sess.

b. HIQ ~ grp + sugg + mtp + sugg:mtp + grp:sugg + grp:mtp + grp:sugg:mtp + (1 | id)

mtp: measurement time point, baseline vs. post third session (enters model equation as factor)

For hypothesis d(i) we investigate the significance of sugg:mtp.

For hypothesis d(ii) we investigate the significance of grp:sugg:mtp.

c. HIQ ~ grp + mtp + grp:mtp + (1 | id)

mtp: measurement time point, post third session vs. one-week follow-up (enters model equation as factor)

For hypothesis b we investigate the significance of grp:mtp.

d. fear ~ grp + sugg + sess + rise + rise^2 + grp:sugg + sess:rise + sess:rise^2 + (rise + rise^2 | id)

sess: first session vs. second session vs. third session (enters as linear predictor)

rise: 20 rises during each of the three sessions, these are entered as a centered variable into the model equation (centered at total mean)

For hypothesis c(i) we investigate the significance of rise and rise^2.

For hypothesis c(ii) we investigate the significance of sess.

For hypothesis c(iii) we investigate the significance of sess:rise.

For hypothesis c(iv) we investigate the significance of sess:rise^2.

For hypothesis c(v) we investigate the significance of grp.

For hypothesis d(iii) we investigate the significance of grp:sugg.

4. Sample Size

- a. Analysis a needs 56 participants to achieve a Power of 80% for the effects of interest.

- b. Analysis **b** needs 92 participants to achieve a Power of 80% for the effects of interest.
- c. Analysis **c** needs 60 participants to achieve a Power of 80% for the effects of interest.
- d. Analysis **d** needs 50 participants to achieve a Power of 80% for the effects of interest.

In order to prevent insufficient Power due to drop-outs, about 10% more participants should be surveyed. A total of 100 participants should therefore be surveyed (50 per group). If it is not possible to survey 100 participants, some of the analyses mentioned above can also be carried out with fewer participants and (as indicated) still enough Power.

5. Exploratory Analyses

- a. Exploratory Relationships:
 - i. More suggestible people report a higher perceived presence in the VR environment than less suggestible people (in both groups).
 - 1. Correlation test (correlation between suggestibility and average experience of presence)
 - ii. More suggestible persons in the experimental group report a higher subjective trance depth than less suggestible persons in the experimental group.
 - 1. Correlation test (correlation between suggestibility and mean trance depth of the experimental group)
- b. Exploratory Analyses:
 - i. We expect a reduction in fear of heights after each session.
 - 1. $\text{HIQ} \sim \text{grp} + \text{mtp} + \text{grp:mtp} + (1 | \text{id})$ (for all sessions)
 - a. mtp: measurement time point, pre vs. post per session
 - ii. We expect that the experimental group shows a lower level of fear of heights in the one-week follow-up than in the pre-measurement of the second session (one-week follow-up after one session). (no investigation of the control group)
 - 1. $\text{HIQ} \sim \text{follow} + (1 | \text{id})$
 - a. follow: pre second session vs. one-week follow-up
 - iii. We also plan to look at how many subjects in the experimental group continue to report a fear of heights below the cut-off for inclusion in the study (HIQ Score > 29) after three months.
- c. Checks:
 - i. We expect no difference in suggestibility between the groups.
 - 1. $\text{sugg} \sim \text{grp} + (1 | \text{id})$
 - ii. We expect no influence of suggestibility on the initial extent of fear of heights
 - 1. $\text{HIQ} \sim \text{sugg} + (1 | \text{id})$
 - iii. We expect no difference in the initial extent of fear of heights between the two groups.
 - 1. $\text{HIQ} \sim \text{grp} + (1 | \text{id})$