19.6.25

Study Protocol

Meaning-centered Intervention (PSY-2324-S-0451)

Procedure

Recruitment will take place through the student-participant pool of the Faculty of Behavioral and Social Sciences at the University of Groningen. Participants for the trial are selected based on an online screening study. After reading the study information and giving consent, participants are screened on i) treatment status ("Are you currently in treatment for a depressive or anxiety disorder?") ii) suicidality (item 9 of the BDI-II; Beck et al. 1996), and iii) depressive and anxiety symptoms per PHQ-4 (Kroenke et al., 2009; Löwe et al., 2014). Participants who display a total score of ≥ 2 on the PHQ-4, who are not in treatment, and do not indicate suicidality were eligible for the trial.

Upon meeting the eligibility criteria, participants were invited to participate in the meaning-centered intervention trial via an email which explains the most important information of the study (e.g. design, content of the meaning-intervention, compensation) and includes a link to the online environment of the baseline assessment. After reading the study information and giving consent, participants fill in demographics (age, gender, nationality, primary language) and their availability for the first intervention session. After that, they fill in a series of questionnaires that are presented in randomized order:

- Meaning in Life Questionnaire (MLQ; Steger et al., 2006)
- Three-dimensional Meaning Scale (3DM; Martela & Steger, 2023)
- Balanced Measure of Psychological Needs (BMPN; Sheldon & Hilpert, 2012)
- Self-control: Brief Self-control Scale (BSCS; Tangney, Baumeister, & Boone, 2004)
- Intolerance of Uncertainty scale (Carlton et al., 2007)
- A Short Boredom Proneness Scale (Struk et al., 2017)
- Depression, Anxiety and Stress Scales–21(DASS-21; Lovibond, 1995)
- Short form of social interaction anxiety scale and social phobia scale (SIAS-6, SPS-6; Peters et al., 2012)
- Loneliness Scale (de Jong-Gierveld & van Tilburg, 1999)
- Robert UCLA Loneliness Scale (Goossens et al., 2014)
- Rosenberg self-esteem scale (Rosenberg, 1979)
- Drinking: Alcohol Use Disorders Identification Test (AUDIT; Saunders, Aasland, Babor, de la Fuente, & Grant, 1993)
- "Govern" subscale of the Temptation and Restraint Inventory (Collins & Lapp, 1992)
- Drinking Motive Questionnaire (Cooper, 1994)
- Drinking Pattern Behaviour (Kurihara et al., 2022)

Then, participants are asked if they were familiar with the names of any intervention trainer involved in the study. Finally, they are thanked for their participation and informed about the next steps. After completing the baseline assessment, they are randomly assigned to either the waitlist or the intervention condition by simple randomization using a true random number

generator (random.org). Participants in the intervention condition are contacted by a trainer that would then conduct the intervention session with them in either Dutch, English, or German. Participants in the intervention condition followed six 1-hour online sessions of a meaning-centered intervention for internalizing symptoms (for details on the original intervention designed for eating disorders, see van Doornik et al., 2024), with sessions taking place approximately every 4 days. Immediately after completion of the last intervention session, participants in the intervention condition will receive the link to the post-assessment questionnaire. Participants in the waitlist condition will be informed that they are assigned to the waitlist condition and that in a month from now they will receive the link to the post-assessment. Waitlist participants will be also informed that they can follow the intervention themselves once data collection completes, prospectively in June 2026. One month after the post-assessment, both conditions will be asked to complete the follow-up assessment. For all assessments, participants will be compensated with SONA credits.

Statistical Analyses

All analyses will be run in R. All analyses will be run as completer analysis, given our aim to assess the efficacy of the present intervention in a subclinical sample (Silverman et al., 2024). Missing values will be imputed using predictive mean matching. Analyses will be run with and without influential observations (i.e., observations showing high standardized residuals and/or leverage). Differences in outcomes between analyses with and without influential points will be reported.

A minimal sample size of N =128 is required to yield power of 0.8 based on testing a one-way ANCOVA with α-level of .05, effect size of f = 0.25, number of groups = 2, max. number of covariates = 2, and numerator df = 1. We aimed to recruit 142 participants, assuming a drop-out rate of 10%.

Primary Outcomes: Meaning in life and Internalizing Symptoms

H1a: The meaning-centered intervention increases meaning in life at post assessment and follow-up, compared to a waitlist control.

H1b: The meaning-centered intervention reduces internalizing symptoms at post assessment and follow-up, compared to a waitlist control.

The effect of the intervention on both meaning and internalizing symptoms will be tested by running a MANCOVA with post-assessment sum score of presence subscale of the MLQ and DASS-21 sum score as dependent variables, with baseline presence sum score and baseline DASS-21 sum score as covariate and condition (intervention, waitlist) as the between-subjects factor. This step will be repeated with the follow-up scores as dependent variables and baseline and post-assessment score as covariates. All resulting p values will be tested against an alpha level of 0.05.

The effect of the intervention specifically on either primary outcome will be tested using ANCOVAs. The first ANCOVA will test the effect on meaning in life, with post-assessment sum score of presence subscale of the MLQ as dependent variable and baseline presence sum score as

covariate, with condition (intervention, waitlist) as a between-subjects factor. This step will be repeated with the follow-up scores as dependent variable and baseline and post-assessment score as covariates.
The effect of the intervention on internalizing symptoms will be tested by an ANCOVA with post-assessment DASS-21 sum score as dependent variable and baseline DASS-21 sum score as covariate, with condition (intervention, waitlist) as a between-subjects factor. This step will be repeated with the follow-up scores as dependent variable and baseline and post-assessment score as covariates.

Secondary Outcomes: Dyscontrolled Drinking and Three-Dimensional Meaning

H2a: The meaning-centered intervention reduces dyscontrolled drinking at post assessment and follow-up, compared to a waitlist control.

H2a: The meaning-centered intervention increases coherence, purpose, and significance at post assessment and follow-up, compared to a waitlist control.

The effect of the intervention on the secondary outcomes dyscontrolled drinking and three-dimensional meaning will be tested using ANCOVAs. The effect on dyscontrolled drinking will be tested using post-assessment sum score of the Govern subscale of the Temptation and Restraint Inventory as dependent variable and baseline Govern sum score as covariate, with condition (intervention, waitlist) as a between-subjects factor. This step will be repeated with the follow-up scores as dependent variable and baseline and post-assessment score as covariates. The effect on three-dimensional meaning will be tested with three ANCOVAs with post-assessment coherence, purpose, and significance sum score as dependent variable and their baseline scores as covariate, with condition (intervention, waitlist) as a between-subjects factor. This step will be repeated with the follow-up scores as dependent variable and baseline and post-assessment score as covariates. The alpha level for the *p* values resulting from the ANCOVAs for the secondary outcomes will be adjusted by Bonferroni-Holm multiple testing correction.

Secondary Analysis: Invariant Causal Prediction
We will analyze the causal relationships between all assessed variables via the Invariant causal prediction (ICP) algorithm (Meinshausen et al., 2016) using code adapted from Kossakowski et al. (2021). The ICP infers causal relationships by testing the residual distribution of a target variable given all possible subsets of predictors against the residual distribution of that variable in the other condition (i.e., intervention or waitlist), using a Kolmogorov-Smirnov test. This procedure is followed for every variable as target variable. Predictors of the target variable which are part of each invariant subset are implied as causes. A subsampling procedure tests which of those relationships hold across random subsamples of participants. We will run the ICP on the post-change scores of all variables. We will also run the ICP on the follow-up-baseline change scores of all variables. Missing data will be imputed using predictive mean matching imputation in the "mice" package (van Buuren & Groothuis-Oudshoorn, 2011). The ICP corrects for familywise error rates using Bonferroni. The ICP will be used for exploratory analysis and inspected for the hypothesized relationships for primary and secondary outcomes described above as well as for the causal link between meaning and internalizing symptoms through intolerance of uncertainty (Ostafin et al., 2022).

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INFORMED CONSENT

“Meaning-centered Intervention”
PSY-2324-S-0451

- I have read the information about the research. I have had enough opportunity to ask questions about it.

- I understand what the research is about, what is being asked of me, which consequences participation can have, how my data will be handled, and what my rights as a participant are.

- I understand that participation in the research is voluntary. I myself choose to participate. I can stop participating at any moment. If I stop, I do not need to explain why. Stopping will have no negative consequences for me.

- Below I indicate what I am consenting to.

Consent to participate in the research:
[ ] Yes, I consent to participate; this consent is valid until 30-06-2026
[ ] No, I do not consent to participate

Consent to processing my personal data:
[ ] Yes, I consent to the processing of my personal data as mentioned in the research information (i.e. SONA ID, e-mail address). I know that until one month after participation I can ask to have my data withdrawn and erased. I can also ask for this if I decide to stop participating in the research.
[ ] No, I do not consent to the processing of my personal data.