Preregistration for Quantitative Research in Psychology (PRP-QUANT) Template

Title

T1 Title
The title should be focused and descriptive, using relevant key terms to reflect what will be done in the study. Use title case (https://apastyle.apa.org/style-grammar-guidelines/capitalization/title-case).
Informed Consent for Psychotherapy: A Randomized Controlled Trial evaluating the Efficacy of an Optimized Informed Consent on Treatment Expectations and Capacity to Consent

T2 Contributors, Affiliations, and Persistent IDs (recommend ORCID iD)
Provide in separate entries the full name of each contributor, each contributor's professional affiliation, and each contributor's persistent ID. See ORCID iD for an example of persistent ID (https://orcid.org/). Optional: include the intended contribution of each person listed (e.g. statistical analysis, data collection; see CRediT, https://casrai.org/credit/).
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T3 Date of Preregistration

This is assigned by the system upon preregistration submission.

T4 Versioning information

This is assigned by the system upon submission of original and subsequent revisions. Should be a persistent identifier, if not a DOI.

T5 Identifier

This unique identifier is assigned by the system upon submission.

T6 Estimated duration of project

Include best estimate for how long the project will take from preregistration submission to project completion.

The ICPT project is expected to last for about 1.5 years from preregistration submission to project completion.

T7 IRB Status (Institutional Review Board/Independent Ethics Committee/Ethical Review Board/Research Ethics Board)

If the study will include human or animal subjects, provide a brief overview of plans for the treatment of those subjects in accordance with established ethical guidelines. If appropriate institutional approval has been obtained for the study, provide the relevant identifier here. If the study will be exempt from ethical board review, provide reasoning here.

The RCT has been designed in line with the CONSORT statement (Schulz et al., 2010) and will be conducted in accordance with the Declaration of Helsinki. Ethical approval is given by the local psychological ethics committee of the Center for Psychosocial Medicine, University-Medical Center Hamburg-Eppendorf, Hamburg, Germany (reference number: LPEK-0292, 01.04.2021).

T8 Conflict of Interest Statement

Identify any real or perceived conflicts of interest with this study execution. For example, any interests or activities that might be seen as influencing the research (e.g., financial interests in a test or procedure, funding by pharmaceutical companies for research).

Despite a general interest in the content related to their field of research, all responsible contributors declare that they have no conflicts of interest.

T9 Keywords

Include terms specific to your topic, methodology, and population. Use natural language and avoid words used in the title or overly general terms. If you need help with keywords, try a keyword search using your proposed keywords in a search engine to check results.

counselling, shared-decision making, risks and side effects of psychotherapy, expectation management, ethics, placebo effect, nocebo effect, efficacy, outpatient psychotherapy

T10 Data accessibility statement and planned repository

"We plan to make the data available (yes / no)
If "yes", please specify the planned data availability level by selecting one of the options:

- Data access via download; usage of data for all purposes (public use file)
- Data access via download; usage of data restricted to scientific purposes (scientific use file)
- Data access via download; usage of data has to be agreed and defined on an individual case basis
- Data access via secure data center (no download, usage/analysis only in a secure data center)
- Data available upon email request by member of scientific community
- Other (please specify)

We plan to make the data available with data access via download: usage of data restricted to scientific purposes (scientific use file).

T11 Optional: Code availability

We plan to make the code available (yes / no).
If "yes", please specify the planned code availability level (use same descriptors of data in T10).

We plan to make the code available with data access via download: usage of data restricted to scientific purposes (scientific use file).

T12 Optional: Standard lab practices

Standard lab practices refer to a (timestamped) document, software package, or similar, which specifies standard pipelines, analytical decisions, etc. which always apply to certain types of research in a lab. Specify here and refer to at the appropriate positions in the remainder of the template:
We plan to make the standard lab practices available (yes / no).
If "yes", please specify the planned standard lab practices availability level (use same descriptors of data in T10).

No.

Abstract

(150 words)

A1 Background

(See introduction I1)

Informed consent is a legal and ethical prerequisite for conducting psychotherapy. However, the informed consent for psychotherapy still seems to play a minor role in daily practice.

A2 Objectives and Research questions

(See introduction I2)

The aim of the present study is to evaluate the efficacy of a newly developed optimized informed consent consultation for psychotherapy (OIC) in a randomized controlled online trial.

A3 Participants

(See methods M4)

N=122 adults with indication for psychotherapy will be recruited.

A4 Study method

(See methods M10-14)

After baseline assessment (t0), participants will be randomly assigned either to a control group receiving an information brochure as treatment as usual (TAU) or to the intervention group receiving the OIC in addition to TAU. OIC and post-assessment will take place at the second online study visit (t1; 2 weeks following t0). Two weeks and three months after t1, participants will receive online follow-up questionnaires. Treatment expectation is the primary outcome. Secondary outcomes include capacity to consent, decisional conflicts, autonomous treatment motivation, and adherence intention.

Introduction

(no word limit)

I1 Theoretical background

Provide a brief overview that justifies the research hypotheses.

Psychotherapists are legally and ethically bound to obtain an informed consent for psychotherapy. To ensure an autonomous consent decision, it is required to provide relevant information about the nature and course of treatment (American Psychological Association, 2017).
In clinical practice, however, the informed consent for psychotherapy is not yet applied as a routine standard (Grady, 2015; Trachsel et al., 2015). Since legal and ethical considerations about the informed consent are of paramount importance, recent research suggests that the informed consent might have so far been underestimated in its clinical relevance to strengthen key predictors of psychotherapy outcome (Trachsel & grosse Holtforth, 2019). This was supported by an experimental pilot study, in which transparent and contextualized information about treatment benefits and potential side effects in an informed consent consultation was found to effectively optimize treatment expectations (Heisig et al., 2015). Recent research also suggests that framing, contextualization, and shared decision-making might represent three promising strategies to optimize informed consent procedures in its legal, ethical, and clinical functionality (Heisig et al., 2015; Barnes et al., 2019; Wells & Kaptchuk, 2012; Krumholz, 2010; Nestoriuc et al., 2021). Nevertheless, advanced approaches for addressing, integrating, and implementing those strategies within the framework of an elaborate informed consent procedure are still missing in clinical practice to this day (Barnes et al., 2019; Evers et al., 2020).

I2 Objectives and Research question(s)

Outline objectives and research questions that inform the methodology and analyses (below).

The planned two-armed randomized controlled online superiority trial investigates the efficacy of a newly developed optimized informed consent procedure (OIC) for psychotherapy in a sample of participants with a treatment indication for psychotherapy. Effects on treatment expectation as primary outcome as well as further secondary clinical outcomes will be assessed and compared between two groups, including a control group receiving an information brochure about psychotherapy as treatment as usual (TAU condition) and an intervention group receiving the OIC in addition to TAU (OIC condition).

I3 Hypothesis (H1, H2, …)

Provide hypothesis for predicted results. If multiple hypotheses, uniquely number them (e.g., H1, H2a, H2b,) and refer to them the same way at other points in the registration document and in the manuscript.

Longitudinal hypotheses:
H1: Treatment expectations increase to a greater extent in the OIC condition than in the TAU condition from baseline (t0) to follow-up assessment (t2).
H2: Decisional conflicts decrease to a greater extent in the OIC condition than in the TAU condition from baseline (t0) to follow-up assessment (t2).
H3: Autonomous treatment motivation increases to a greater extent in the OIC condition than in the TAU condition from baseline (t0) to follow-up assessment (t2).
H4: The adherence intention increase to a greater extent in the OIC condition than in the TAU condition from baseline (t0) to follow-up assessment (t2).
H5: Expectations of the occurence of side effects of psychotherapy decrease to a greater extent in the OIC condition than in the TAU condition from baseline (t0) to follow-up assessment (t2).
H6: Expectations of coping with side effects of psychotherapy increase to a greater extent in the OIC condition than in the TAU condition from baseline (t0) to follow-up assessment (t2).
H7: Anxiety of experiencing side effects of psychotherapy decreases to a greater extent in the OIC condition than in the TAU condition from baseline (t0) to follow-up assessment (t2).
H8: The interest in participating in psychotherapy increases to a greater extent in the OIC condition than in the TAU condition from baseline (t0) to follow-up assessment (t2).
H9: The perceived knowledge about psychotherapy increases to a greater extent in the OIC condition than in the TAU condition from baseline (t0) to follow-up assessment (t2).

Cross-sectional hypotheses:
H10: The capacity to consent is higher in the OIC condition compared to the TAU condition at post assessment (t1).
H11: The subjective satisfaction with received information is higher in the OIC condition compared to the TAU condition at post assessment (t1).

I4 Exploratory research questions (if applicable; E1, E2, ...)

If planning exploratory analyses, provide rationale for them here. If multiple exploratory analyses, uniquely number them (E1, E2, ...) and refer to them in the same way in the registration document and in future publications.

E1: Is the effort for treatment services higher in the OIC condition compared to the TAU condition at 3-months follow-up (t3)?
E2: Is the utilization of treatment services higher in the OIC condition compared to the TAU condition at 3-months follow-up (t3)?
E3: Are the treatment expectations higher in the OIC condition compared to the TAU condition at 3-months follow-up (t3)?

E4: Which (expected) adverse events are reported by study participants? Do participants of the OIC condition report less (expected) adverse events compared to the participants of the TAU condition at post-assessment (t1), 2-week (t2) and 3-months follow-up (t3)?
E5: Which (expected) severe adverse events are reported by study participants? Do participants of the OIC condition report less severe adverse events compared to the participants of the TAU condition at 3-months follow-up (t3)?

Method

M1 Time point of registration

Select one of the options:

- Registration prior to creation of data
- Registration prior to any human observation of the data
- Registration prior to accessing the data
- Registration prior to analysis of the data
- Other (please specify; might include if T1 longitudinal data has been analyzed, but T2 has not yet been analyzed)

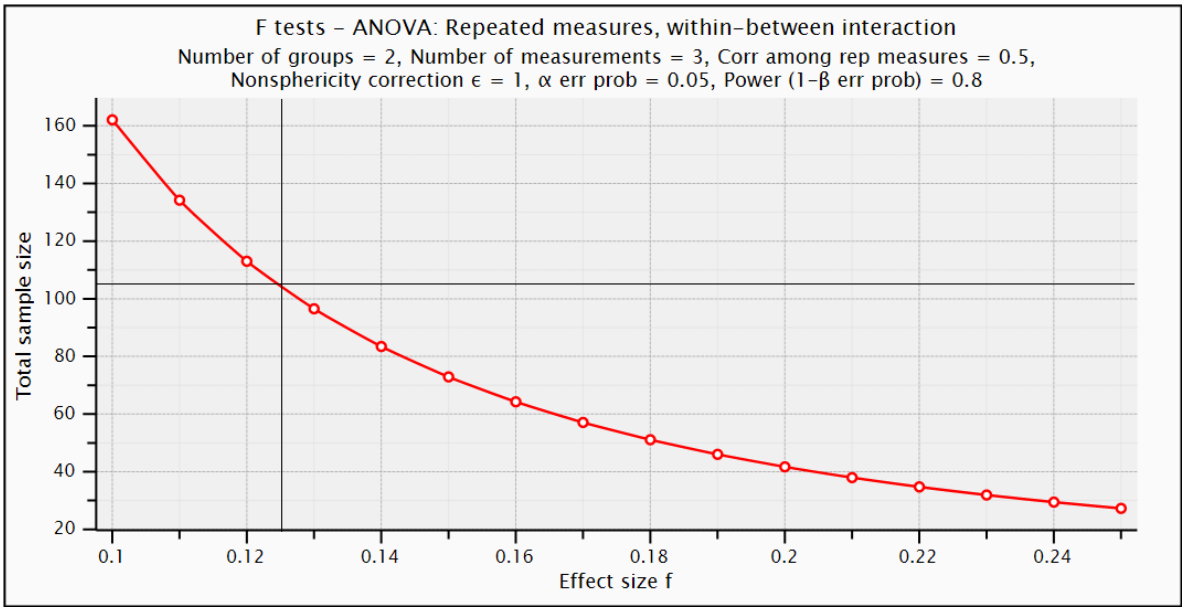
Prospective registration prior to creation of data

M2 Proposal: Use of pre-existing data (re-analysis or secondary data analysis)

Will pre-existing data be used in the planned study? If yes, indicate if the data were previously published and specify the source of the data (e.g., DOI or APA style reference of original publication). Specify your level of knowledge of the data (e.g., descriptive statistics from previous publications), whether or not this is relevant for the hypotheses of the present study, and how it is assured that you are unaware of results or statistical patterns in the data of relevance to the present hypotheses.

No pre-existing data will be used in the planned study.

Sampling Procedure and Data Collection

M3 Sample size, power and precision
(1) Relevant sample sizes: e.g., single groups, multiple groups, and sample sizes (or sample ranges) found at each level of multilevel data. (2) Provide power analysis (e.g. power curves) for fixed-N designs. For sequential designs, indicate your 'stopping rule' such as the points at which you intend to be viewing your data and in any way analyzing them (e.g., t-tests and correlations, but even descriptively such as with histograms).
(1) A total of *N* = 122 participants with an indication for psychotherapy will be recruited and randomly assigned to one of two groups, with an anticipated *n* = 61 in each of the two groups. (2) The software package G*Power was used to calculate the required sample size a priori. For two-tailed testing and an alpha level of α = 0.05, *N* = 106 participants would provide an 80% power to detect significant and small to medium interaction and main effects of *f* = 0.125 on the primary outcome (see figure 1). An oversampling with an anticipated dropout rate of 15% is considered for the targeted sample size of *N* = 122 (*n* = 61 per group). **Figure 1** *Power plot for a priori total samples sizes in a repeated measures ANOVA with within-between interaction*    *Note.* Number of groups = 2, Number of measurements = 3, Correlation among repeated measures = 0.5, alpha level of α = 0.05, Power (1-ß) = 0.8.

M4 Participant recruitment, selection, and compensation

Indicate (a) methods of recruitment (e.g., subject pool advertisement, community events, crowdsourcing platforms, snowball sampling); (b) selection and inclusion/exclusion criteria (e.g., age, visual acuity, language facility); (c) details of any stratification sampling used; (d) planned participant characteristics (gender, race/ethnicity, sexual orientation and gender identity, SES, education level, age, disability or health status, geographic location); (e) compensation amount and method (e.g., same payment to all, pay based on performance, lottery).

(a) Recruitment will be primarily realized by a cooperation with the Outpatients Clinics of the Center for Psychosocial Medicine at the University Medical Center Hamburg-Eppendorf. In addition, participants will be recruited through referrals of other cooperating outpatient centers, physicians, psychotherapists, mailing lists, internet platforms, and social media platforms.
(b) Inclusion criteria:
(1) ≥18 years of age
(2) Indication for psychotherapy (at least one suspected diagnosis according to DSM-5),
(3) Availability of an email account and a web-connected device with a camera (video signal) and a microphone (audio signal)
(4) Informed consent for study participation and for providing an audio record
Exclusion criteria:
(1) Current utilization of in- or outpatient psychotherapy
(2) Utilization of probatory sessions for psychotherapy within the last four weeks
(3) Insufficient language comprehension
(4) Insufficient attention span and/or cognitive capacity for participating in the interviews and the OIC
(5) Acute suicidality
(c) The type of prior experiences with psychotherapy (negative vs. no vs. positive prior experiences with psychotherapy) will be used as a stratification variable.
(d) At least 18-years old participants will be included in the trial with no preference given to their gender, race/ethnicity, sexual orientation, gender identity, socioeconomic status, and educational level.
(e) Participants will not receive any financial compensation. However, they may receive an oral feedback or written report about their individual results of the clinical interview on demand.

M5 How will participant drop-out be handled?

Indicate any special treatment for participants who drop out (e.g., there is follow-up in a manner different from the main sample, last value carried forward) or whether participants are replaced.

An oversampling of 15% is considered to ensure that at least 106 valid cases can be included in the main analyses. In line with the CONSORT guidelines, both intention-to-treat and per-protocol analyses will be conducted on all outcomes obtained. Moreover, all dropout cases with the corresponding time points of and reasons for dropout will be clearly and thoroughly documented. The post-assessments and the follow-up questionnaires for participants who drop out will be conducted the same way as for all other participants.

M6 Masking of participants and researchers

Indicate all forms of masking and/or allocation concealment (e.g., administrators, data collectors, raters, confederates are unaware of the condition to which participants were assigned).

Due to the nature of the study, neither the participant nor the conducting study psychologist can be masked. Thus, the study psychologist will be aware of the study condition to which the participant has been randomly assigned. All statictical analyses of the trial as well as assessments of capacity to consent and individual adverse events will be performed assessor blinded.

M7 Data cleaning and screening

Indicate all steps related to data quality control, e.g., outlier treatment, identification of missing data, checks for normality, etc.

Due to the nature of the planned online assessments, errors in data entry can be precluded for all self-report questionnaires. The data obtained from the MacCAT-T interview as well as the suspected diagnoses according to DSM-5 obtained from the clinical interview are entered manually. Data entry will be performed according to a script and following individual training. After data entry, 10% of the data will be continuously monitored by another member of the study team. If the number of mistakes exceeds 5% per case, another 10% of the data will be additionally monitored. Plausibility checks will be performed before subsequently conducting any statistical analyses. Model assumptions of linear mixed modelling (homoscedasticity, normally distributed residuals, outliers, sphericity) will be the subject of prior analyses. If outliers are identified, results of the analyses including outliers are compared with those obtained from analyses excluding outliers. Proportions of missing at random and missing not at random values will be analyzed on the case- and variable-level.

M8 How will missing data be handled?

Indicate any procedures that will be applied during the analysis to deal with missing data, such as (a) case deletions; (b) averaging across scale items (to handle missing items for some); (c) test of missingness (MAR, MCAR, MNAR assumptions; (d) imputation procedures (FIML vs. MI); (e) Intention-to-treat analysis and per protocol analysis (as appropriate).

Proportions of missing values will be analyzed per person and variable. The MCAR assumption will be tested using Little's MCAR Test. Missing values are substituted using multiple imputation, if more than 2% of data is missing. In case of multiple imputation, the performed intention-to-treat analyses will be compared to per-protocol analyses (exclusion of participants who have discontinued treatment) as part of a sensitivity analysis. If 2% or less of the data is missing, no data will be imputed and a sensitivity analysis will be carried out based on the last observation carried forward method.

M9 Other information (optional)

For example, training of raters/participants or anything else not yet specified.

Study psychologists who will conduct the semi-structured clinical interview (SCID-5) and the interview for the assessment of consent ability, will take part in respective interviewer and rating trainings prior to the study. Moreover, study psychologists will be trained to conduct the OIC. All trainings will be guided by a licensed psychological psychotherapist and supervisor.

Conditions and design

M10 Type of study and study design

Indicate the type of study (e.g., experimental, observational, crosssectional vs. longitudinal, single case, clinical trial) and planned study design (e.g., between vs. within subjects, factorial, repeated measures, etc.), number of factors and factor levels, etc.

This study is an experimental clinical superiority trial investigating the efficacy of an optimized informed consent consultation. Linear mixed modelling with treatment condition as the between-subject factor (2 factor levels: OIC vs. TAU condition) and time as the within-subject factor (3 factor levels: t0, t1, t2) will be conducted.

M11 Randomization of participants and/or experimental materials

If applicable, describe how participants are assigned to conditions or treatments, how stimuli are assigned to conditions, and how presentation of tests, trials, etc. is randomized. Indicate the randomization technique and whether constraints were applied (pseudo-randomization). Indicate any type of balancing across participants (e.g., assignments of responses to hands, etc.).

Stratification by prior experiences with psychotherapy (positive vs. no vs. negative prior experiences) will be used as a proper sampling technique to ensure that individuals with varying treatment experiences receive proper representation in both treatment conditions. Provided that treatment experiences are then equally distributed across both trial arms, group comparisons on the clinical outcomes will be adjusted for group differences in treatment experience.

Stratified permuted block randomization with a block size of 4 will be used to randomize participants 1:1 to the OIC and TAU conditions. The randomization sequences will be generated by a researcher who is otherwise not involved in the study conduction prior to the first enrolment using an online program. At the end of the first online study visit, the researcher determines the stratum based on the patient's statement and then performs the allocation.

M12 Measured variables, manipulated variables, covariates

This section shall be used to unambiguously clarify which variables are used to operationalize the hypotheses specified above (item I3). Please (a) list all measured variables, and (b) explicitly state the functional role of each variable (i.e., independent variable, dependent variable, covariate, mediator, moderator). It is important to (c) specify for each hypothesis how it is operationalized, i.e., which variables will be used to test the respective hypothesis and how the hypothesis will be operationally defined in terms of these variables. The description here shall be consistent with the statistical analysis plans specified under AP6 (below).

Outcomes:
H1: Treatment expectations (primary outcome) will be assessed by the Treatment Expectation Questionnaire (TEX-Q). The questionnaire consists of 15 items presented on an 11-point Likert scale ranging from 0 to 10.
H2: Decisional conflicts will be assessed by the Decisional Conflict Scale (DCS). The DCS includes 16 items presented on a 5-point Likert scale from “not correct at all” to “fully correct”.
H3: Autonomous treatment motivation will be assessed by the subscale “Autonomous motivation” of the Autonomous Motivation for Therapy Scale (ACMTQ). The subscale consists of six items presented on a 7-point Likert scale from “strongly disagree” to “strongly agree”.
H4: Adherence intention will be assessed by three self-developed items presented on an 11-point Likert scale ranging from “0 - not sure at all” to “10 - absolutely sure”.
H5-7: Expectations of the occurrence of and coping with side effects of psychotherapy, as well as the anxiety of experiencing side effects will be each assessed by one self-developed item presented on an 11-point Likert scale ranging from 0 to 10.
H8: The interest in participating in psychotherapy will be assessed by one self-developed item presented on an 11-point Likert scale ranging from 0 to 10.
H9: The perceived knowledge about psychotherapy will be assessed by one self-developed item presented on an 11-point Likert scale ranging from 0 to 10.
H10: The capacity to consent will be assessed by the MacArthur Competence Assessment Tool for Treatment (MacCAT-T interview). The MacCAT-T is a semi-structured interview including four specific domains, namely understanding, reasoning, appreciation, and expressing a choice. Subscale scores, ranging from 0 to 6 (understanding), 0 to 8 (reasoning), 0 to 4 (appreciation), and 0 to 2 (choice), as well as the total sum score, ranging from 0 to 20, will be used for analyses.
H11: Satisfaction with received information will be assessed by the German version of the Client Satisfaction Questionnaire (CSQ-8). The eight items are presented on a 4-point Likert scale.
E1: The effort for treatment services will be assessed by 3 self-developed items presented on a 7-point Likert scale ranging from “strongly disagree” to “strongly agree”.
E2: The utilization of treatment services will be assessed by 6 self-developed items with the response options “yes” and “no”.
E4: Adverse events will be assessed using a short interview, which will be conducted by a blinded study psychologist at post assessment. Three a priori developed items about potential harms (feeling confused, feeling frightened about potential negative effects of psychotherapy, experiencing doubts about the decision to start psychotherapy) will be assessed in addition to open questions about further individual adverse events. Each event will be rated by the interviewer according to severity (5 point likert scale) and its potential causal relationship to the study participation (5 point likert scale). For follow-up assessments (t2 and t3), the three a priori defined potential harms and further individual

adverse events are assessed via self-report according to severity (5 point likert scale) and its potential causal relationship to the study participation (5 point likert scale).
E5: Serious adverse events will be assessed using a short interview, which will be conducted by a blinded study psychologist at post assessment. Three a priori developed items about potential harms (suicidal ideation, self harm, hospitalisation) will be assessed in addition to open questions about further individual adverse events. Each event will be rated by the interviewer according to severity (5 point likert scale) and its potential causal relationship to the study participation (5 point likert scale). For follow-up assessments (t2 and t3), the three a priori defined potential harms and further individual serious adverse events are assessed via self-report according to severity (5 point likert scale) and its potential causal relationship to the study participation (5 point likert scale).

Potential covariates:
1. The respective baseline score on the investigated outcome variable.
2. The stratification variable type of prior experiences with psychotherapy will be assessed by the Generic rating scale for previous treatment experiences, treatment expectations, and treatment effects (GEEE). Scores obtained from the GEEE will be recoded into a new categorical variable including the categories “no previous experiences with psychotherapy”, “rather negative prior experiences with psychotherapy”, and “rather positive prior experiences with psychotherapy”.
3. The perceived therapeutic relationship will be assessed by the subscale “satisfaction with relationship” of the Helping Alliance Questionnaire (HAQ). The HAQ subscale consists of 6 items with six response options (1 = strongly disagree to 6 = strongly agree).
4. State anxiety will be assessed by the section “state” of the State-Trait-Angst-Depressions-Inventar (STADI). The section consists of 20 statements with four response options (1 = not at all to 4 = very much).
5. The time of occupation with the information brochure (TAU) in minutes will be assessed by participants’ self-reports.
6. Prior knowledge about psychotherapy will be assessed by the subscale “knowledge” of the Fragebogen zur Psychotherapiemotivation (FPTM). The subscale contains four items with four response options (1 = agree to 4 = fully disagree).

Other variables:
1. Sociodemographic characteristics (age, gender, marital status, education level, and occupational status) will be assessed by participants’ self-reports.
2. Psychopathology (suspected diagnoses according to DSM-5) will be evaluated by the SCID-5 interview.
3. The intake of mental health medication will be assessed by the SCID-5 interview.

M13 Study Materials

Please describe any relevant study materials. This could include, for example, stimulus materials used for experiments, questionnaires used for rating studies, training protocols for intervention studies, etc.

Participants of the OIC condition will be provided with visual information cards as part of the optimized informed consent consultation. These cards will be sent by mail. The questionnaires will be made available via the web-based software EFS Survey.

M14 Study Procedures

Please describe here any relevant information about how the study will be conducted, e.g., the number and timing of measurement time points for longitudinal research, the number of blocks or runs per session of an experiment, laboratory setting, the group size in group testing, the number of training sessions in interventional studies, questionnaire administration for online assessments, etc.

Participants will take part in two online study visits within an interval of two weeks and two web-based follow-up assessments two weeks and three months later. Prior to enrollment, interested people are screened for elegibility via telephone interviews. People who fulfill self-reportable eligibility criteria will be invited for the first of two online study visits. Both online study visits are conducted by trained clinicians. At the first online study visit (t0), written information about the study will be given and the self-reportable in- and exclusion criteria will be queried. After participants have given their informed consent, they will take part in a video-based Structured Clinical Interview for DSM-5 Disorders (SCID-5; Beesdo-Baum et al., 2019) to verify the indication for psychotherapy and check for exclusion criteria. If participants fulfill the eligibility criteria, the baseline assessment (t0) as well as the subsequent randomization will take place. At the end of t0, participants of both groups will receive the TAU in the form of an information brochure about psychotherapy. Participiants will be invited to voluntarily study the brochure at their discretion until the second online study visit (t1) two weeks later. At the second online study visit (t1), participants in the OIC condition will take part in the video-based OIC conducted by trained clinicians. Afterwards, all participants will take part in the post assessment and an audiotaped interview for assessing the capacity to consent. Upon request, participants may receive their individual results report of the SCID-5 within one week after t1. Two weeks (t2) and three months (t3) after t1, participants will be invited to complete two online follow-up questionnaires. For queries and problems during the consent procedure and the completion of the questionnaires, members of the study team will be available via telephone or email to handle requests in a timely manner.

M15 Other information (optional)

Analysis plan

(NOTE: If this varies by hypothesis, repeat analysis plan for each)

AP1 Criteria for post-data collection exclusion of participants, if any

Describe all criteria that will lead to the exclusion of a participant's data (e.g. performance criteria, non-responding in physiological measures, incomplete data). Be as specific as possible.

In line with the intention-to-treat approach, participants' data will be analyzed irrespective of participants' non-compliance, withdrawal, or losses to follow-up (Fergusson et al., 2002). According to the recommendations by Fergusson et al. (2002), participant's data will be excluded from analyses, if ineligible participants are mistakenly included in either trial.

AP2 Criteria for post-data collection exclusions on trial level (if applicable)

Describe all criteria that will lead to the exclusion of a trial or item (e.g. statistical outliers, response time criteria). Be as specific as possible.

Not applicable.

AP3 Data preprocessing

Describe all data manipulations that are performed in preparation of the main analyses, e.g. calculation of variables or scales, recoding, any data transformations, preprocessing steps for imaging or physiological data (or refer to publicly accessible standard lab procedure, cf. T12).

Prior to the main analyses, respective overall scores (mean or sum scores) of the self-report measures will be calculated. Suspected diagnoses will be evaluated using the SCID-5 interview in accordance to DSM-5 diagnostic criteria. Additionally, a blinded rater will evaluate the capacity to consent by the audio transcript of the conducted MacCAT-T interview and calculate an overall sum score.

AP4 Reliability analysis (if applicable)

Specify the type of scale reliability that will be estimated, whether it is internal consistency (e.g. Cronbach's alpha, omega), test-retest reliability, or some other form (e.g., a confirmatory factor analysis incorporating multiple factors as sources of variance). In a study involving measure development, researchers should specify criteria for removing items from measures a priori (e.g., largest factor loading magnitude, smallest drop in alpha-if-item removed).

Internal consistency of all scales provided by the self-report questionnaires will be indicated by Cronbach's alpha. Moreover, the interrater-reliability of the MacCAT-T interview will be assessed by evaluating the degree of agreement and homogeneity among raters.

AP5 Descriptive statistics

Specify which descriptive statistics will be calculated for which variables. If appropriate, specify which indices of effect size will be used. If descriptive statistics are linked to specific hypotheses, explicitly link the information given here to the respective hypothesis.

In order to ensure the comparability of groups at baseline, subsamples will be checked for possible between-group differences in both sociodemographic and clinical characteristics using either independent sample *t*-tests, Welch's *t*-tests or respectively, Mann-Whitney *U*-tests for continuous variables and Pearsons's chi-square tests for categorical variables.

AP6 Statistical models (provide for each hypothesis if varies)

Specify the statistical model (e.g. t test, ANOVA, LMM) that will be used to test each of your hypotheses. Give all necessary information about model specification (e.g., variables, interactions, planned contrasts) and follow-up analyses. Include model selection criteria (e.g., fit indices), corrections for multiple testing, and tests for statistical violations, if applicable. Wherever unclear, describe how effect sizes will be calculated (e.g., for d-values, use the control SD or the pooled SD).

With the exception of H10, H11, and E1-E5, all hypotheses will be tested by conducting a linear mixed model for repeated measures. In line with the intention-to-treat approach, all randomized participants will be included in the analyses. The mixed ANOVA will include the between-subject factor treatment condition (OIC condition vs. TAU condition) and the within-subject factor time (t0, t1, t2). Prior to linear mixed modeling, additional variables (e.g. respective baseline scores, type of prior experiences with psychotherapy, prior knowledge about psychotherapy, satisfaction with the therapeutic relationship, state anxiety, and the time of occupation with the information brochure) are checked for significant associations with the respective outcomes to identify potential covariates. Significant covariates will be included in the respective linear mixed model. Group differences will be investigated by Tukey post-hoc tests. In case of unequal group sizes, Bonferroni-corrected post-hoc tests will be performed instead.

Exceptions from the aforementioned analytical approach refer to the cross-sectional hypotheses for the secondary outcomes capacity to consent and satisfaction with received information (H10 and H11). In order to test for both, group differences at post-assessment (t1) will be examined by conducting an independent sample *t*-test, a Welch's *t*-test or a Mann-Whitney *U*-test. Between-group differences at baseline will be tested using independent sample *t*-tests, Welch's *t*-tests or respectively, Mann-Whitney *U*-tests for continuous variables and Pearsons's chi-square tests for categorical variables.
The proportion of the variance in the respective outcome variables that can be explained by the variance in the independent variables will be indicated by partial eta squared and for pairwise comparisons, Cohen's *d* will be reported as a common measure of effect size.

AP7 Inference criteria

Specify the criteria used for inferences (e.g., p values, Bayes factors, effect size measures) and the thresholds for accepting or rejecting your hypotheses. If possible, define a smallest effect size of interest. If inference criteria differ between hypotheses, specify separately for each hypothesis and respective statistical model by explicitly referring to the numbers of the hypotheses. Describe which effect size measures will be reported and how they are calculated.

Statistical significance of the analyzed effects will be accepted and the respective null hypotheses will be rejected at a significance level of $\alpha \leq 5\%$. In addition to the indication of statistical significance, a set of different coefficients will be calculated to evaluate the effect size. Thus, Cohen's *d* will be reported for pairwise comparisons, with $d = 0.20$ indicating small, $d = 0.50$ indicating moderate, and $d = 0.80$ indicating large effects (Cohen, 1988). Cohen's *d* will be determined by standardized mean differences, thus calculating the mean score difference between the groups to be compared and dividing the result by the pooled standard deviation. Partial eta squared will be reported for estimating the proportion of explained variance for hypotheses H1-H9, with $\eta^2 = 0.01$ indicating small, $\eta^2 = 0.06$ indicating moderate, and $\eta^2 = 0.14$ indicating large effects (Cohen, 1988).

AP8 Exploratory analysis (optional)

Describe any exploratory analyses to be conducted with your data. Include here any planned analyses that are not confirmatory in the sense of being a direct test of one of the specified hypotheses.

To investigate the exploratory hypotheses E1-E4, group differences at t1, t2 and t3 will be examined by conducting an independent sample *t*-test, a Welch's *t*-test or a Mann-Whitney *U*-test. To investigate the exploratory hypothesis E5, group differences at t3 will be examined by conducting a Kruskal-Wallis test or a Mann-Whitney *U*-test.

References

R1 References

Enter your references below. Use a consistent format (e.g., https://apastyle.apa.org/style-grammar-guidelines/references/examples)

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