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# Optimizing Treatment Expectations and Decision Making Through Informed Consent for Psychotherapy: A Randomized Controlled Trial

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***Objective:*** The objective of this research was to determine the efficacy and safety of an optimized informed consent (OIC) consultation for psychotherapy. ***Method:*** We performed a randomized controlled superiority online trial involving 2 weeks of treatment and 3 months of follow-up. One hundred twenty-two adults with mental disorders confirmed by structured interview currently neither in out- nor inpatient psychotherapy (mean age: 32, gender identity: 51.6% female, 1.6% diverse), were randomized. Participants received an information brochure about psychotherapy for self-study (treatment as usual [TAU]; $n = 61$) or TAU plus a one-session OIC utilizing expectation management, contextualization, framing, and shared decision making ($n = 61$). The primary outcome was treatment expectations at 2-week follow-up. ***Results:*** At 2-week follow-up, participants receiving OIC showed more positive treatment expectations compared to those receiving TAU only (mean difference: 0.70, 95% CI [0.36, 1.04]) with a medium effect size ($d = 0.73$). Likewise, OIC positively influenced motivation ($d = 0.74$) and adherence intention ($d = 0.46$). OIC entailed large effects on reduction of decisional conflict ($d = 0.91$) and increase of knowledge ($d = 0.93$). Participants receiving OIC showed higher capacity to consent to treatment ($d = 0.63$) and higher satisfaction with received information ($d = 1.34$) compared to TAU. No statistically significant group differences resulted for expected adverse effects of psychotherapy. Results were maintained at 3-month follow-up. Data sets for $n = 10$ cases (8.2%) were missing (postassessment $n = 4$, 2-week $n = 6$, 3-month follow-up $n = 8$). ***Conclusions:*** Explaining to patients how psychotherapy works via a short consultation was effective in strengthening treatment expectations and decision making in a nonharmful way. Further trials clarifying whether this effectively translates to better treatment outcomes are required.

***What is the public health significance of this article?***
Among patients with mental disorders, an optimized informed consent consultation was superior to treatment as usual in promoting adequate treatment expectations, motivation, and capacity to consent to treatment while decreasing decisional conflict. Results support the efficacy and safety of an optimized informed consent using expectation management, contextualization, framing, and shared decision making among patients with mental disorders. The 35-min informed consent consultation can be easily implemented within trial sessions for a psychotherapy. This study highlights the clinical relevance of explaining to patients how psychotherapy works.

*Keywords:* ethics, risks and side effects, counseling, treatment expectations, decision making

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*continued*

Psychotherapy, like medical treatments, requires informed consent. In clinical practice, temporal constraints and formal language can weaken a necessary focus on promoting patients' understanding and autonomous decision making, thereby leading to poor consent quality (Grady, 2015; Hall et al., 2012; Spatz et al., 2016). So far, evidence-based guidelines to implement informed consent for psychotherapy are missing (Blease et al., 2018). The process of informed consent takes place mainly before (e.g., during trial sessions) but also during psychotherapeutic treatment (Pomerantz, 2005). In preliminary consultations prior to any treatment, patients should be informed of all circumstances essential to consent (German Civil Code, 2013). In clinical practice, information about expected benefits, common factors, or risks of psychotherapy is rarely disclosed while organizational aspects seem overrepresented (Dsubanko-Obermayr & Baumann, 1998; Gerke, Meyrose, et al., 2022). Consequently, patients might not acquire realistic treatment expectations, which in turn, weakens therapeutic alliance (Barber et al., 2014; Johansson et al., 2011; Zilcha-Mano & Fisher, 2022) and leads to poorer psychotherapy outcome (Constantino et al., 2018; Seligman et al., 2009). For legal reasons, patients' mere signatures might be considered as appropriate informed consent. However, degrading informed consent to nothing but a legal obligation underestimates its ethical and clinical value (Jefford & Moore, 2008; Trachsel & Grosse Holtforth, 2019).

Five elements of valid informed consent have been proposed in biomedical ethics: patient's decision-making capacity, information disclosure, understanding, voluntariness, and the explicit statement of consent (Beauchamp & Childress, 2019). Accordingly, a comprehensive information disclosure requires a preceding evaluation of patient's decision-making capacity. Due to interindividual differences in patients' capacity to consent, a one-size-fits-all approach seems insufficient. Health care providers are encouraged to protect and reinforce patients' right to self-determination by an explicit statement of consent (Krumholz, 2010). Applying these principles while disclosing information about the nature and course, potential risks, side effects, and treatment alternatives as well as information about efficacy, benefits, and mechanisms of action remains challenging (American Psychological Association [APA], 2017; European Federation of Psychologists' Associations [EFPA], 2005). In line, clinicians frequently report reservations about the validity and feasibility of informed consent for psychotherapy (Blease et al., 2020; Eberle et al., 2021).

A comprehensive informed consent has the clinical potential to strengthen relevant psychotherapy-related outcomes. First, balanced information about expected benefits and risks may promote positive yet realistic treatment expectations (Constantino et al., 2018). Second, patients who are informed about treatment alternatives and patients' rights might develop higher treatment motivation (Blease et al., 2018; Trachsel & Grosse Holtforth, 2019). Third, transparent information might strengthen treatment credibility, thereby contributing to adherence and alliance (Blease et al., 2022; Trachsel et al., 2015). Fourth, individualizing information and actively weighing advantages and disadvantages can promote capacity to consent and reduce decisional conflict (Stacey et al., 2017). Finally, information about potential risks might enable patients and clinicians not only to recognize and communicate adverse events but also to develop adequate coping strategies (Bingel, 2014; Michnevich et al., 2022). To actively counteract unwanted nocebo effects, that is, causing harm by provoking unwanted effects through negative treatment expectations, techniques such as contextualization (e.g., embedding risk information in information about efficacy and mechanisms of action), and framing (e.g., explaining initial worsening of symptoms at therapy onset as a sign of efficacy) seem promising (Barnes et al., 2019; Wells & Kaptchuk, 2012; Zech et al., 2022). Although informed consent is a prerequisite for psychotherapy, evidence-based implementations of an ethically sound informed consent and experimental investigations of its impact on psychotherapy-related outcomes and decision making are missing. Therefore, the present trial aims to investigate the efficacy and safety of a newly developed, optimized informed consent (OIC) in participants with an indication for psychotherapy. We hypothesize that OIC leads to significantly better psychotherapy-related outcomes such as treatment expectations and decision-related outcomes compared to treatment as usual (TAU) at 2-week follow-up (primary end point).

## Method

### Study Design and Participants

In this superiority randomized controlled online trial, participants with an indication for psychotherapy were randomly allocated 1:1

relationships with any organizations that might have an interest in the submitted work; no other relationships or activities that could appear to have influenced the submitted work.

The data sets generated during the present study will be available in anonymized form for scientific purposes in the publicly available Repository PsychArchives. All data and research materials will be available for scientific purposes in the publicly available Disciplinary Repository for Psychological Science PsychArchives (https://www.psycharchives.org/). Prospectively registered at PsychArchives; http://doi.org/10.23668/psycharchives.4929.

Leonie Gerke played a lead role in data curation, formal analysis, project administration, visualization, and writing–original draft and an equal role in conceptualization and investigation. Franz Pauls played a lead role in methodology, a supporting role in conceptualization, data curation, formal analysis, project administration, and supervision, and an equal role in writing–review and editing. Sönke Ladwig played a supporting role in conceptualization, data curation, formal analysis, methodology, project administration, and visualization and an equal role in investigation and writing–review and editing. Sarah Liebherz played a supporting role in investigation, project administration, and resources and an equal role in writing–review and editing. Klaus Michael Reininger played a supporting role in investigation, project administration, and resources and an equal role in writing–review and editing. Levente Kriston played a supporting role in data curation, formal analysis, methodology, and software and an equal role in supervision and writing–review and editing. Manuel Trachsel played a supporting role in conceptualization, methodology, and resources and an equal role in supervision and writing–review and editing. Martin Härter played a supporting role in conceptualization, formal analysis, methodology, project administration, resources, and supervision and an equal role in writing–review and editing. Yvonne Nestoriuc played a lead role in funding acquisition, resources, supervision and writing–review and editing, a supporting role in data curation, formal analysis, investigation, methodology, project administration, and software and an equal role in conceptualization.

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either to receive an information brochure about psychotherapy for self-study (TAU) or to receive TAU in combination with the OIC. After recruitment of the a priori calculated sample size of $N = 122$ from August 2021 until July 2022, follow-up data were collected until December 2022. The trial's design and hypotheses were preregistered on 17th June 2021 in the repository PsychArchives (http://doi.org/10.23668/psycharchives.4929) and received approval from the local ethics committee of the Centre for Psychosocial Medicine, University Medical Centre Hamburg-Eppendorf, Germany (reference number: LPEK-0292, April 1, 2021). All participants provided written informed consent for participation online. The study protocol provides a detailed description of methods (Gerke, Ladwig, et al., 2022).

We included individuals with at least one diagnosis according to the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM-5*), who were 18 years or older, had an email account and a web-connected device with camera and microphone, provided informed consent for study participation and audio recording, and had sufficient cognitive capacity to participate in the interviews and the OIC. Exclusion criteria included current out- or inpatient psychotherapy, probatory sessions within the last 4 weeks, and acute suicidality. To increase accessibility and reduce health risks due to the ongoing COVID-19 pandemic, the OIC was applied online via Red Medical, a secure video service provider. Recruitment was carried out in cooperation with the Institute of Psychotherapy of the University Medical Center Hamburg-Eppendorf, an outpatient clinic specialized both in psychodynamic and cognitive behavioral psychotherapy, leaflets distributed in doctors' offices for general practice, pharmacies, and counseling centers, via internet platforms (e.g., https://www.psychenet.de/de/), a reference in a magazine article, and social media (Instagram, Reddit). Participants recruited through the outpatient clinics had preregistered for an initial psychotherapy consultation and did not receive any incentives such as an earlier appointment as compensation for study participation. In social media, posts were primarily published in general groups (e.g., in relation to German cities) and, as a supplement, in specific psychology-related groups. In order to exclude participation motives other than interest in psychotherapy, participants gained no financial compensation for expenses.

## Randomization and Reduction of Bias

A randomizing officer who was not involved in study conduction performed stratified permuted block randomization with a block size of four using a web-based application. Participants were allocated 1:1 to OIC and TAU with prior experience with psychotherapy (none vs. positive vs. negative) as stratum. Patient-reported outcomes were collected online and filled in without contact to members of the study team to control for assessment bias. Psychotherapists conducted trainings with study psychologists and interviewers for the OIC and the MacArthur Competence Assessment Tool for Treatment interview and provided ongoing supervision.

## Power Analysis

Based on a previous experimental study analyzing the effects of framing and personalizing information about endocrine treatment on side-effect expectations in healthy women (Heisig et al., 2015), we a priori calculated the required sample size using the software G*Power with an expected small-to-medium effect size for the impact of the OIC on the primary outcome (treatment expectations). For two-tailed testing and a predetermined alpha level of $\alpha = .05$, $N = 106$ participants would provide 80% power to detect significant interaction and main effects of $f = 0.125$ on the primary outcome. To compensate for an anticipated dropout rate of 15%, a total sample of $N = 122$ participants was determined to be randomly assigned to one of two groups ($n = 61$ per group).

## Transparency and Openness

We report all data exclusions for sensitivity analyses, all manipulations, and all measures in the study, and we follow the APA Style Journal Article Reporting Standards (Kazak, 2018). All data and research materials will be available for scientific purposes in the publicly available Disciplinary Repository for Psychological Science PsychArchives (https://www.psycharchives.org/).

## Procedure

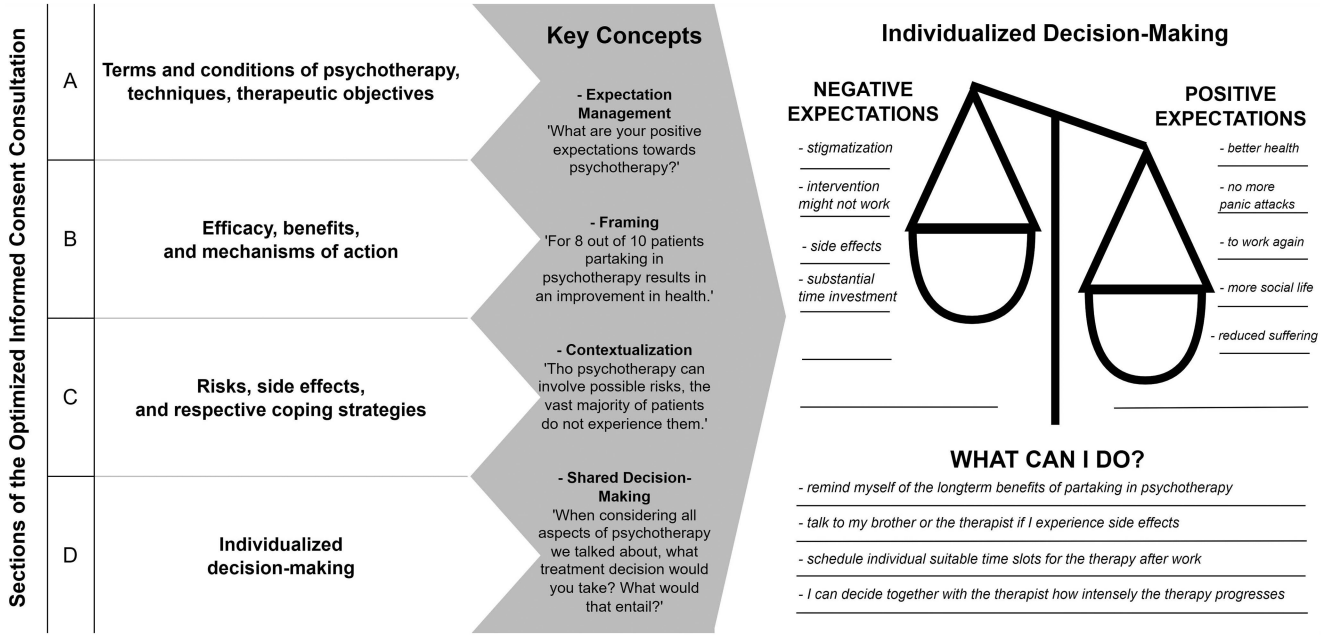
Interested individuals took part in a video-based structured clinical interview for *DSM-5* disorders (Beesdo-Baum et al., 2019) including all diagnostic sections with a typical duration of 45–90 min. After verifying the indication for psychotherapy and checking exclusion criteria, eligible participants took part in the baseline assessment (T0), subsequent randomization, and received TAU. Two weeks later, participants in the OIC group attended the one-session OIC performed by the same study psychologist who conducted the clinical interview. Subsequently, participants in both groups took part in the postassessment (T1) via online questionnaires and an audiotaped interview via Red Medical for assessing capacity to consent. At 2-week (T2; primary outcome time point) and 3-month follow-up (T3), participants completed online questionnaires.

## Interventions

The OIC was developed as a new clinical tool for psychotherapists to obtain informed consent in preliminary consultations prior to psychotherapy. The development of the OIC was based on a literature review of legal and ethical requirements (APA, 2017; EFPA, 2005; German Civil Code, 2013), expectation and psychotherapy research evidence (Blease et al., 2021; Evers et al., 2018; Rief, 2021). Information was arranged into four sections (see Figure 1): (a) terms and conditions, techniques, and therapeutic objectives; (b) efficacy, benefits, mechanisms of action; (c) risks, side effects, and respective coping strategies; and (d) individualized decision making. In iterative consultations with master students of psychology, strategies of expectation management, framing, contextualization, and shared decision making were pretested and gradually embedded into the OIC sections. The two conducting study psychologists with master's degrees participated in the development of the intervention. Clinicians with different psychotherapeutic backgrounds provided feedback on the visual information cards and the prototyped manualized OIC. Two eligible persons with lived experience regarding mental disorders pretested the OIC to account for comprehensibility and feasibility. Finally, the two study psychologists were intensively trained by a licensed psychotherapist and the project team to conduct the 35-min OIC according to the semistructured treatment manual

**Figure 1**

*Structure of the Optimized Informed Consent Consultation*




(see Supplemental 1). Participants received the information cards before the scheduled OIC per mail.

In Section a (approx. 12 min), expectation management and individualization were applied by addressing prior psychotherapeutic experiences and respective expectations. Study psychologists provided general information about psychotherapy adapted to individual information needs and supported participants in naming and writing down own treatment goals. In Section b (approx. 8 min), information about the efficacy and mechanisms of action was presented gain-framed instead of loss-framed (e.g., "roughly eight out of ten people who undergo psychotherapy experience an improvement in their state of health greater than those who have not undergone therapy"; Federal Chamber of Psychotherapists in Germany, 2021). Such statistics were visually mapped by person charts on the information cards. Data on the general treatment effectiveness of psychotherapy were consistent with those in the information brochure (TAU; Federal Chamber of Psychotherapists in Germany, 2021). That is, psychotherapy is an evidence-based treatment and verifiably effective, in fact, more effective than many treatments for physical illnesses. Additionally, study psychologists provided information that patients with mental illnesses discontinue psychotherapy less frequently than those undergoing drug therapy and that the effects of psychotherapy are more lasting than those of medication (Federal Chamber of Psychotherapists in Germany, 2021). In Section c (approx. 5 min), information about risks and side effects was embedded into information about the efficacy using examples (e.g., initial symptom deterioration) and metaphors (e.g., muscle soreness). All participants received the core message that psychotherapy is evidence-based and effective, and that like other effective treatments, psychotherapy might entail risks and side effects. In Section c (approx. 10 min), participants were actively involved in the discussion and weighing of personal treatment advantages, disadvantages, and alternative treatment options using contextualization and shared decision making. In the shared decision-making process, participants were actively encouraged to name and write down their positive and negative expectations about psychotherapy. When negative expectations arose, study psychologists assisted participants in developing concrete coping strategies (e.g., seeking discussion with the therapist). To meet the conditions of a preliminary psychotherapeutic consultation, the decision-making process focused on whether or not to engage in psychotherapeutic treatment as a dichotomous decision. If indicated, alternative treatment options such as psychopharmacological treatment or low-threshold counseling services were discussed. In line with the ethical principle of patient autonomy, study psychotherapists explicitly addressed the treatment decision to be made and actively encouraged participants to make an autonomous and informed treatment decision. As the centerpiece of the intervention, participants were asked in terms of a balance model whether the individually collected advantages or disadvantages weighed more heavily for them personally and how they would decide (psychotherapeutic treatment yes/no) after everything has been discussed.

In both trial conditions, participants received an 80-page information brochure about psychotherapy from the Federal Chamber of Psychotherapists in Germany via email as TAU (Federal Chamber of Psychotherapists in Germany, 2021). The information brochure is freely available in German, English, and Turkish language on the website of the Federal Chamber of Psychotherapists (https://bptk.de/pressemitteilungen/bptk-patientenin formation-wege-zur-psychotherapie/). The information brochure is divided into nine sections: (1) *Am I mentally ill?*, (2) *psychotherapeutic consultations*, (3) *acute care*, (4) *the trial sessions*, (5) *outpatient psychotherapy*, (6) *treatment in hospital*,

(7) *medical rehabilitation*, (8) *who pays?—applications and costs*, and (9) *your rights as a patient* (Federal Chamber of Psychotherapists in Germany, 2021). The content of the information brochure was consistent with that of the OIC (e.g., on the effectiveness of psychotherapy). However, information of the information brochure was more comprehensive and more focused on organizational aspects than in the OIC.

## Outcomes

*Psychotherapy-related outcomes* included the primary outcome *treatment expectations* assessed using the Treatment Expectation Questionnaire (Alberts et al., 2020; Shedden-Mora et al., 2023). Items can be assigned to six subscales: Treatment benefit, Positive impact, Adverse events, Negative impact, Process, and Behavioral control. The primary outcome *treatment expectations* was operationalized by the mean total score of the Treatment Expectation Questionnaire, ranging from 0 to 10, with higher scores indicating higher treatment expectations.

The subscale Autonomous Motivation of the Autonomous and Controlled Motivations for Treatment Questionnaire (Zuroff et al., 2007) was translated by a team of three researchers including one native speaker to assess autonomous treatment motivation. During pretranslation and back-translation, any discrepancies were reviewed and discussed within the team. Three items presented on an 11-step numeric rating scale were developed to assess participants' *adherence intention* to psychotherapy. The effort for and utilization of treatment services were assessed by four self-developed items with binary response option (yes/no) at T3.

*Decision-related outcomes* included *decisional conflict* with the Decisional Conflict Scale (Buchholz et al., 2011). Items are assigned to five domains: uncertainty, informed, values clarity, support, and effective decision. *Capacity to consent to treatment* was assessed with the semistructured MacArthur Competence Assessment Tool for Treatment interview adapted for psychotherapy (Grisso et al., 1997; Vollmann, 2008). *Knowledge about psychotherapy* was assessed with five self-developed items presented on an 11-step numeric rating scale. The Client Satisfaction Questionnaire (Attkisson & Zwick, 1982; Schmidt et al., 1989) was used to assess *satisfaction with received information*.

*Safety outcomes* included three items presented on an 11-step numeric rating scale adapted from the Generic rating scale for previous treatment experiences, treatment expectations, and treatment effects (G-EEE; Rief et al., 2021) to assess *expectations about experiencing adverse effects of psychotherapy*, *anxiety about experiencing adverse effects*, and *expectations about coping with adverse effects*. In line with recent recommendations about adverse event recording (Papaioannou et al., 2021), we a priori defined three potential *adverse events* of study participation (i.e., feeling confused, feeling frightened about potential negative effects of psychotherapy, experiencing doubts about the decision to start psychotherapy) and three *serious adverse events* (i.e., suicidal ideation, self-harm, hospitalization) that were assessed by six interview items with binary response options (yes/no). If an adverse event was affirmed, participants rated its severity and causal relationship to study participation (in terms of TAU including video-based Structured Clinical Interview for *DSM-5*, online questionnaires and an audiotaped interview; in terms of OIC group, additionally including the OIC). Moreover, participants were asked about other adverse events using open questions. At follow-ups, the same items were assessed via an online self-rating questionnaire instead of an interview.

## Statistical Analyses

Analyses were conducted for the intention-to-treat sample, which included all participants who completed the baseline assessment. For the primary outcome, we fitted a linear mixed model for repeated measures, which used all available information and assumed that data were missing at random conditional on information in the model. We used a restricted maximum likelihood estimation with a diagonal residual covariance structure including time, group, and their interaction as fixed effects, and the intercept as a random effect to model interindividual differences regarding the average level of the outcome. The stratification variable was included as a covariate (factor). Mean differences in the estimated marginal means (MD), their standard errors (*SE*), and *t*-statistics were calculated for all comparisons of OIC to TAU at T1, T2, and T3. Standardized between-group effect sizes (Cohen's *d*; Cohen, 1988) were calculated by dividing the model-based group difference by the pooled standard deviations for the observed data of the two groups. All tests were performed two-sided with an $\alpha$ error of 0.05. Data analyses were conducted using IBM SPSS Statistics software Version 27 (IBM Inc., Armonk, NY).

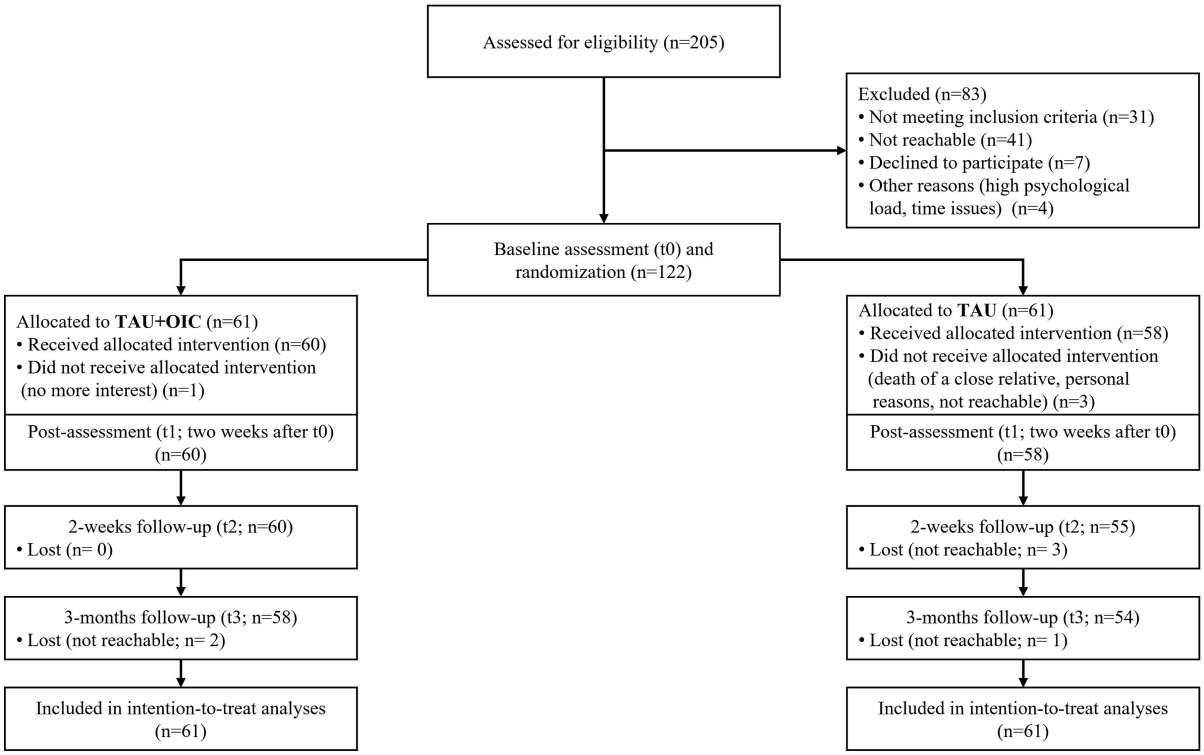
In absence of repeated measurements (i.e., interview about capacity to consent, satisfaction with received information), we used multiple imputation with 15 imputations based on sociodemographic (sex, age) and other variables (e.g., treatment expectations, decisional conflict) as predictors. To examine between-group differences in outcomes measured only at single time points, independent sample *t* tests were performed. Intergroup differences for categorical variables were detected using Pearson chi-square tests. Given the exploratory nature of the secondary outcome analyses, we chose to report uncorrected *p* values for all outcomes. In two sensitivity analyses, we repeated the primary analyses including (a) only participants with complete data sets (T0–T3; $n = 112$) and (b) sex, number of diagnoses, and prior knowledge about psychotherapy as covariates. In an additional analysis, we investigated possible differences between the study psychologists by repeating the primary analyses including time, group, experimenter, and their interactions as fixed effects or in absence of repeated measurements, including group, experimenter, and their interaction as fixed effects. Deviations from the study protocol (Gerke, Ladwig, et al., 2022) are reported in Supplemental eTable 1.

# Results

## Descriptives

Most participants were recruited through social media (60.7%), followed by the cooperating outpatients clinics (19.7%), internet platforms (7.4%), recommendations from acquaintances (4.1%), reference in a magazine article (4.1%), and leaflets distributed in counseling centers and doctors' offices (2.5%). Recruitment information was missing for two participants (1.6%). Four participants (3.3%) dropped out after T0 (see Figure 2). One of them participated at T2 and T3. Three participants (2.5%) dropped out after T1, of whom one participated at T3. Additional three participants (2.5%) dropped out after T2.

**Figure 2**
*Flow of Participants*




*Note*. The data reported in this article have not been previously published. TAU = treatment as usual; OIC = optimized informed consent; t1 = postassessment; t2 = 2-week follow-up; t3 = 3-month follow-up.

Participants mean age was 31.97 years ($SD$ = 10.91). In terms of gender identity, 51.6% reported to be female, 46.7% male, and 1.64% diverse. More than half were single (52.5%), and 41.8% had a university degree. On average, participants had 2.22 mental disorders according to *DSM-5* ($SD$ = 1.08), with depressive and anxiety disorders being the most common. 43.4% reported having prior experience with psychotherapy, 28.7% reported positive, and 14.8% negative experiences. There were no statistically significant baseline group differences on any demographic or clinical variables (see Table 1). However, participants in TAU tended to be more female/diverse, have more diagnoses, and know more about psychotherapy. At T1, participants reported having spent an average of 19.84 min ($SD$ = 23.31) reading and processing the information brochure with no significant differences ($t_{83.16} = -1.10$, $p = .275$) between OIC ($M$ = 17.50, $SD$ = 14.80) and TAU ($M$ = 22.26, $SD$ = 29.62). In the TAU group, 20 of 58 participants (34.5%) stated that they had not dealt with the information brochure. Data were missing for three participants in TAU. In the OIC group, 14 of 60 participants (23.3%) stated that they had not dealt with the information brochure. For one participant in the OIC group, data were missing.

## Psychotherapy-Related Outcomes

Efficacy results are depicted in Table 2. OIC was significantly associated with more positive treatment expectations than TAU at T1 (MD = 0.66, 95% CI [0.33, 1.04], $p < .001$; $d = 0.66$), T2 (MD = 0.70, 95% CI [0.36, 1.04], $p < .001$; $d = 0.73$), and T3 (MD = 0.58, 95% CI [0.19, 0.97], $p = .004$; $d = 0.53$). Pairwise comparisons revealed statistically significant higher autonomous treatment motivation[1] in OIC compared to TAU at T1 ($p < .001$; $d = 0.84$) and T2 ($p < .001$; $d = 0.74$), indicating medium-to-large effects. Participants receiving OIC showed higher adherence intention (see Footnote 1) compared to TAU at T1 ($p < .001$; $d = 0.65$) and T2 ($p = .010$; $d = 0.46$), indicating small-to-medium effects. The effort for and utilization of treatment services did not differ between OIC and TAU at T3 (Supplemental eTable 2).

## Decision-Related Outcomes

Decisional conflict (see Footnote 1) was found to be lower for OIC compared to TAU at T1 ($p < .001$; $d = 1.43$) and T2 ($p < .001$; $d = 0.91$), indicating large effects. Pairwise comparisons indicated statistically significantly higher levels of knowledge about psychotherapy (see Footnote 1) in OIC compared to TAU at T1 ($p < .001$; $d = 1.26$) and T2 ($p < .001$; $d = 0.93$), indicating large effects. At T1, participants receiving OIC showed a statistically significant higher *capacity to consent to treatment*[2] compared to TAU, indicating a medium effect size ($p < .001$, $d = 0.63$). Compared to TAU, *satisfaction with received information*

[1] Not assessed at T3.
[2] Not assessed at T2 or T3.

**Table 1**
*Sociodemographic and Clinical Characteristics of the Sample at Baseline (N = 122)*

| Characteristics | OIC, *N* (%) | TAU, *N* (%) | Group comparison |
|---|---|---|---|
| Gender identity | | | $\chi^2(2) = 3.26$, $p = .196$ |
| Female | 29 (47.54) | 34 (55.74) | |
| Male | 32 (52.46) | 25 (40.98) | |
| Diverse | 0 (0.00) | 2 (3.28) | |
| Age in years, *M* (*SD*) | 31.36 (10.77) | 32.57 (11.10) | $t(120) = 0.61$, $p = .542$ |
| Marital status | | | $\chi^2(2) = 1.14$, $p = .931$ |
| In a partnership | 26 (42.62) | 24 (39.34) | |
| Single | 31 (50.83) | 33 (54.10) | |
| Divorced | 4 (6.56) | 4 (6.56) | |
| Highest education | | | $\chi^2(3) = 2.65$, $p = .448$ |
| No school degree | 0 (0.00) | 1 (1.64) | |
| Middle school | 13 (21.31) | 9 (14.75) | |
| High school | 21 (34.43) | 27 (44.26) | |
| University | 27 (44.26) | 24 (39.34) | |
| Employment status | | | $\chi^2(3) = 1.96$, $p = .581$ |
| Employed | 34 (55.74) | 32 (52.46) | |
| Unemployed/homemaker | 5 (8.20) | 10 (16.39) | |
| Student/in training | 21 (34.43) | 18 (29.51) | |
| Retired | 1 (1.64) | 1 (1.64) | |
| Intake of mental health medication | 8 (13.11) | 12 (19.67) | $\chi^2(1) = 0.96$, $p = .328$ |
| Diagnoses[a] | | | |
| Depressive disorders | 44 (72.13) | 41 (67.21) | |
| Anxiety disorders | 24 (39.44) | 32 (52.46) | |
| Trauma- and stressor-related disorders | 17 (27.87) | 15 (24.59) | |
| Substance-related and addictive disorders | 10 (16.39) | 19 (31.15) | |
| Neurodevelopmental disorders (here: ADHD) | 13 (21.31) | 13 (21.31) | |
| Bipolar disorders | 5 (8.20) | 6 (9.84) | |
| Obsessive–compulsive and related disorders | 2 (3.28) | 9 (14.75) | |
| Somatic symptom and related disorders | 4 (6.56) | 4 (6.56) | |
| Eating disorders | 4 (6.56) | 2 (3.28) | |
| Sleep–wake disorders | 1 (1.64) | 3 (4.91) | |
| Disruptive, impulse control, and conduct disorders | 1 (1.64) | 0 (0.00) | |
| Number of diagnoses[a], *M* (*SD*) | 2.07 (1.00) | 2.38 (1.14) | $t(120) = 1.60$, $p = .111$ |
| Prior experiences with psychotherapy | | | $\chi^2(2) = 0.04$, $p = .979$ |
| No prior experience | 35 (57.38) | 34 (55.74) | |
| Positive experience | 17 (27.87) | 18 (29.51) | |
| Negative experience | 9 (14.75) | 9 (14.75) | |
| Prior knowledge about psychotherapy[b] (5–20), *M* (*SD*) | 12.21 (3.39) | 13.28 (3.46) | $t(120) = 1.72$, $p = .088$ |
| Satisfaction with relationship to the study psychologist[c] (6–36), *M* (*SD*) | 31.00 (3.71) | 30.61 (4.20) | $t(120) = -0.55$, $p = .585$ |

*Note.* TAU = treatment as usual; OIC = optimized informed consent consultation; ADHD = attention-deficit/hyperactivity disorder.
[a] Diagnoses were assessed according to the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM-5*) using the *Structured Clinical Interview for DSM-5 Disorders-Clinician version*. Participants could receive multiple diagnoses. [b] Sum score of the subscale Knowledge of the Questionnaire on Psychotherapy Motivation, ranging from 5 to 20, with higher scores indicating higher knowledge. [c] Sum score of the subscale Relation to the Therapist of the Helping Alliance Questionnaire, ranging from 6 to 36, with higher scores indicating higher satisfaction with the therapeutic relationship.

(see Footnote 2) was statistically significantly higher in OIC at T1, indicating a large effect ($p < .001$, $d = 1.33$).

## Safety Outcomes

At T1, participants in OIC reported higher *expectations regarding coping with adverse effects* ($p = .004$; $d = 0.49$). This difference was not statistically significant at baseline ($p = .436$) or T2 ($p = .054$). There were no other statistically significant differences in *expected adverse effects of psychotherapy* ($p = .343$–$.716$) or *anxiety about adverse effects* ($p = .628$–$.888$) between OIC and TAU at any measurement point (see Table 2).

An overview of reported adverse events of study participation is shown in Table 3. No statistically significant group differences were found for "feeling confused" and "experiencing doubts about the decision to start psychotherapy" at T1, T2, and T3. Directly after the OIC (T1), nine participants in OIC (15%) and two participants in TAU (3.45%) reported to be afraid of adverse psychotherapeutic effects, revealing a statistically significant group difference ($p = .031$). This difference was not statistically significant 2 weeks

**Table 2**
*Results of the Analysis of the Longitudinal Primary and Secondary Outcomes*

| | Observed data | | | | | | Estimated values (ITT) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | TAU | | | OIC | | | TAU | | | OIC | | | | | | | |
| | | | | | | | | [95% CI] | | | [95% CI] | | | [95% CI] | | | |
| Time point | *n* | *M* | *SD* | *n* | *M* | *SD* | EMM | *LL* | *UL* | EMM | *LL* | *UL* | MD | *LL* | *UL* | *p* value | Cohen's *d* |
| **Psychotherapy-related outcomes** | | | | | | | | | | | | | | | | | |
| Treatment expectations (primary outcome)[a] | | | | | | | | | | | | | | | | | |
| T0 | 61 | 6.65 | 1.10 | 61 | 6.88 | 0.98 | | | | | | | | | | | |
| T1 | 58 | 6.58 | 1.18 | 60 | 7.28 | 0.86 | 6.59 | 6.34 | 6.84 | 7.27 | 7.02 | 7.52 | 0.68 | 0.33 | 1.04 | <.001 | 0.66 |
| T2 | 56 | 6.63 | 1.07 | 60 | 7.28 | 0.85 | 6.57 | 6.33 | 6.81 | 7.26 | 7.03 | 7.50 | 0.70 | 0.36 | 1.04 | <.001 | 0.73 |
| T3 | 56 | 6.61 | 1.23 | 58 | 7.16 | 0.96 | 6.59 | 6.31 | 6.87 | 7.17 | 6.90 | 7.45 | 0.58 | 0.19 | 0.97 | .004 | 0.53 |
| Autonomous treatment motivation[b] | | | | | | | | | | | | | | | | | |
| T0 | 61 | 5.14 | 0.90 | 61 | 5.41 | 0.84 | | | | | | | | | | | |
| T1 | 58 | 5.07 | 0.94 | 60 | 5.80 | 0.71 | 5.10 | 4.90 | 5.30 | 5.81 | 5.60 | 6.01 | 0.71 | 0.42 | 0.99 | <.001 | 0.85 |
| T2 | 56 | 5.06 | 1.09 | 60 | 5.73 | 0.70 | 5.06 | 4.82 | 5.31 | 5.73 | 5.49 | 5.97 | 0.67 | 0.33 | 1.01 | <.001 | 0.74 |
| Adherence intention[c] | | | | | | | | | | | | | | | | | |
| T0 | 61 | 7.89 | 1.92 | 61 | 8.21 | 1.35 | | | | | | | | | | | |
| T1 | 58 | 7.71 | 1.95 | 60 | 8.73 | 0.94 | 7.76 | 7.37 | 8.15 | 8.75 | 8.36 | 9.14 | 0.99 | 0.46 | 1.54 | <.001 | 0.65 |
| T2 | 56 | 7.76 | 2.03 | 60 | 8.43 | 1.29 | 7.68 | 7.26 | 8.10 | 8.45 | 8.04 | 8.86 | 0.77 | 0.18 | 1.36 | .010 | 0.46 |
| **Decision-related outcomes** | | | | | | | | | | | | | | | | | |
| Decisional conflict[d] | | | | | | | | | | | | | | | | | |
| T0 | 61 | 41.01 | 16.68 | 61 | 40.01 | 16.62 | | | | | | | | | | | |
| T1 | 58 | 39.25 | 17.52 | 60 | 19.22 | 9.99 | 39.37 | 35.80 | 42.94 | 19.08 | 15.54 | 22.62 | −20.29 | −25.32 | −15.26 | <.001 | 1.43 |
| T2 | 56 | 33.15 | 18.09 | 60 | 19.38 | 12.28 | 33.16 | 29.21 | 37.12 | 19.23 | 15.36 | 23.11 | −13.93 | −19.47 | −8.39 | <.001 | 0.91 |
| Knowledge about psychotherapy[e] | | | | | | | | | | | | | | | | | |
| T0 | 61 | 4.93 | 1.81 | 61 | 4.43 | 1.89 | | | | | | | | | | | |
| T1 | 58 | 4.91 | 1.84 | 60 | 6.95 | 1.45 | 4.90 | 4.47 | 5.32 | 6.98 | 6.56 | 7.40 | 2.08 | 1.49 | 2.68 | <.001 | 1.26 |
| T2 | 56 | 5.52 | 1.93 | 60 | 7.12 | 1.49 | 5.56 | 5.12 | 6.00 | 7.15 | 6.72 | 7.58 | 1.59 | 0.97 | 2.20 | <.001 | 0.93 |
| **Safety outcomes[f]** | | | | | | | | | | | | | | | | | |
| Expected adverse effects of psychotherapy[g] | | | | | | | | | | | | | | | | | |
| T0 | 61 | 3.34 | 2.54 | 61 | 2.93 | 2.21 | | | | | | | | | | | |
| T1 | 58 | 3.28 | 2.55 | 60 | 3.43 | 2.05 | 3.34 | 2.77 | 3.90 | 3.48 | 2.93 | 4.04 | 0.15 | −0.64 | 0.94 | .716 | 0.06 |
| T2 | 56 | 3.52 | 2.17 | 60 | 3.35 | 1.89 | 3.62 | 3.00 | 4.16 | 3.40 | 2.87 | 3.92 | −0.23 | −0.98 | 0.52 | .550 | −0.11 |
| Anxiety about adverse effects[g] | | | | | | | | | | | | | | | | | |
| T0 | 61 | 3.10 | 3.02 | 61 | 2.84 | 2.95 | | | | | | | | | | | |
| T1 | 58 | 2.90 | 2.85 | 60 | 2.93 | 2.67 | 2.94 | 2.29 | 3.59 | 3.00 | 2.36 | 3.65 | 0.07 | −0.85 | 0.98 | .888 | 0.02 |
| T2 | 56 | 3.07 | 2.49 | 60 | 2.95 | 2.40 | 3.21 | 2.54 | 3.87 | 3.02 | 2.36 | 3.68 | −0.19 | −1.12 | 0.75 | .692 | −0.08 |
| Expectations regarding coping with adverse effects[g] | | | | | | | | | | | | | | | | | |
| T0 | 61 | 6.72 | 2.15 | 61 | 7.03 | 2.26 | | | | | | | | | | | |
| T1 | 58 | 6.36 | 2.15 | 60 | 7.32 | 1.60 | 6.39 | 5.94 | 6.84 | 7.31 | 6.87 | 7.76 | 0.92 | 0.29 | 1.56 | .004 | 0.49 |
| T2 | 56 | 6.64 | 1.93 | 60 | 7.22 | 1.59 | 6.57 | 6.10 | 7.04 | 7.21 | 6.76 | 7.67 | 0.64 | −0.01 | 1.30 | .054 | 0.37 |

*Note.* Linear mixed effects models adjusted for the valence of prior psychotherapeutic experience. TAU = treatment as usual; OIC = optimized informed consent consultation in combination with TAU; T0 = baseline; T1 = postassessment; T2 = 2-week follow-up; T3 = 3-month follow-up; EMM = estimated marginal mean; MD = between-group difference of estimated marginal means; *LL* = lower limit; *UL* = upper limit; CI = confidence interval; ITT = intention-to-treat.
[a] Mean total score of the *Treatment Expectation Questionnaire*, ranging from 0 to 10, with higher scores indicating higher treatment expectations. [b] Mean score of the subscale Autonomous Motivation of the Autonomous and Controlled Motivations for Treatment Questionnaire, ranging from 1 to 7, with higher scores indicating higher autonomous motivation. [c] Mean score of three self-developed items, ranging from 0 to 10, with higher scores indicating higher adherence intention. [d] Total score of the *Decisional Conflict Scale*, ranging from 0 to 100, with higher scores indicating higher decisional conflict. [e] Mean score of five self-developed items, ranging from 0 to 10, with higher scores indicating higher levels of knowledge about psychotherapy. [f] Results of the analyses of a priori defined possible adverse effects of study participation are reported in Table 3 und in the Supplemental 2. [g] Self-developed item, ranging from 0 to 10, with higher scores indicating higher expectations about experiencing adverse effects, anxiety about experiencing adverse effects, or expectations about coping with adverse effects.

**Table 3**

*Results for a Priori Defined Potential AE of Study Participation at Postassessment via Video Interview and at Follow-Ups via Online Questionnaire*

| | OIC ($n$ = 60) | | | TAU ($n$ = 58) | | | |
|---|---|---|---|---|---|---|---|
| Postassessment (T1) | Occurrence $n$ (%) (yes/no) | Severity[a] $M$ (*SD*) (1–5) | Causality[b] $M$ (*SD*) (1–5) | Occurrence $n$ (%) (yes/no) | Severity[a] $M$ (*SD*) (1–5) | Causality[b] $M$ (*SD*) (1–5) | Comparison (occurrence) test statistics |
| Adverse events | | | | | | | |
| Feeling confused | 10 (16.67) | 2.90 (1.20) | 1.20 (0.42) | 8 (13.79) | 2.63 (1.06) | 1.75 (1.39) | $\chi^2(1) = 0.19$, $p = .664$ |
| Anxiety about negative effects of psychotherapy | 9 (15.00) | 2.56 (0.73) | 2.56 (1.74) | 2 (3.45) | 1.50 (0.71) | 3.00 (2.83) | $\chi^2(1) = 4.66$, $p = .031$ |
| Doubts about decision to start psychotherapy | 5 (8.33) | 1.20 (0.45) | 1.80 (1.79) | 10 (17.24) | 1.60 (0.70) | 2.70 (1.42) | $\chi^2(1) = 2.11$, $p = .146$ |
| Serious adverse events | | | | | | | |
| Suicidal ideation | 5 (8.33) | 3.80 (1.10) | 1.00 (0.00) | 6 (10.34) | 2.83 (0.41) | 1.67 (1.21) | $\chi^2(1) = 0.14$, $p = .707$ |
| Self-harm | 1 (1.67) | 4.00 (0.00) | 1.00 (0.00) | 3 (5.17) | 2.00 (1.00) | 1.00 (0.00) | $\chi^2(1) = 1.11$, $p = .293$ |
| Hospitalization | 0 (0.00) | — | — | 2 (3.45) | 3.00 (2.83) | 1.00 (0.00) | $\chi^2(1) = 2.11$, $p = .147$ |
| Other adverse events, for example, physical diseases, quarrels with significant others, stress in daily life | 25 (41.67) | 3.33 (0.88) | 2.11 (1.69) | 29 (50.00) | 3.46 (1.07) | 1.46 (0.95) | $\chi^2(1) = 0.83$, $p = .364$ |
| Adverse events per person, $M$ (*SD*) | 0.95 (1.02) | 3.00 (1.10) | 1.88 (1.51) | 1.14 (1.22) | 2.88 (1.22) | 1.71 (1.21) | $t(116) = 0.91$, $p = .364$ |
| 2-week follow-up (T2) | OIC ($n$ = 60) | | | TAU ($n$ = 56) | | | Comparison |
| Adverse events | | | | | | | |
| Feeling confused | 17 (28.33) | 3.00 (0.79) | 3.00 (1.17) | 15 (26.79) | 2.67 (0.82) | 2.47 (1.25) | $\chi^2(1) = 0.04$, $p = .852$ |
| Anxiety about negative effects of psychotherapy | 7 (11.67) | 2.43 (0.79) | 2.86 (1.35) | 9 (16.07) | 3.22 (0.97) | 2.89 (1.62) | $\chi^2(1) = 0.47$, $p = .492$ |
| Doubts about decision to start psychotherapy | 10 (16.67) | 2.10 (0.88) | 2.40 (1.17) | 17 (30.36) | 2.29 (1.16) | 2.76 (1.09) | $\chi^2(1) = 3.04$, $p = .081$ |
| Serious adverse events | | | | | | | |
| Suicidal ideation | 5 (8.33) | 2.80 (1.10) | 2.00 (0.71) | 8 (14.29) | 2.88 (1.25) | 1.50 (0.76) | $\chi^2(1) = 1.03$, $p = .310$ |
| Self-harm | 1 (1.67) | 3.00 (0.00) | 2.00 (0.00) | 0 (0.00) | — | — | $\chi^2(1) = 0.94$, $p = .332$ |
| Hospitalization | 0 (0.00) | — | — | 1 (1.79) | 2.00 (0.00) | 1.00 (0.00) | $\chi^2(1) = 1.08$, $p = .299$ |
| Other adverse events, for example, end of relationships, quarrels with significant others, fears about world political developments | 14 (23.33) | 3.93 (0.92) | 1.86 (1.10) | 16 (28.57) | 3.68 (1.11) | 2.05 (1.58) | $\chi^2(1) = 0.41$, $p = .520$ |
| Adverse events per person, $M$ (*SD*) | 0.90 (1.04) | 2.98 (1.05) | 2.46 (1.19) | 1.23 (1.29) | 2.94 (1.16) | 2.35 (1.36) | $t(114) = 1.53$, $p = .129$ |
| 3-month follow-up (T3) | OIC ($n$ = 58) | | | TAU ($n$ = 56) | | | Comparison |
| Adverse events | | | | | | | |
| Feeling confused | 16 (27.59) | 3.06 (0.85) | 2.38 (1.26) | 17 (30.36) | 3.00 (0.79) | 1.59 (0.71) | $\chi^2(1) = 0.11$, $p = .744$ |
| Anxiety about negative effects of psychotherapy | 7 (12.07) | 2.71 (0.76) | 2.14 (1.35) | 12 (21.43) | 2.92 (0.79) | 2.08 (1.24) | $\chi^2(1) = 1.80$, $p = .180$ |
| Doubts about decision to start psychotherapy | 18 (31.03) | 2.39 (1.04) | 1.78 (1.17) | 20 (35.71) | 2.50 (0.76) | 2.15 (1.18) | $\chi^2(1) = 0.28$, $p = .596$ |
| Serious adverse events | | | | | | | |
| Suicidal ideation | 7 (12.07) | 3.00 (1.15) | 1.86 (1.22) | 9 (16.07) | 3.33 (0.71) | 1.44 (0.73) | $\chi^2(1) = 0.38$, $p = .539$ |
| Self-harm | 2 (3.45) | 3.00 (0.00) | 2.00 (1.41) | 2 (3.57) | 2.50 (0.71) | 1.00 (0.00) | $\chi^2(1) = 0.00$, $p = .972$ |
| Hospitalization | 3 (5.17) | 2.33 (0.58) | 2.33 (1.53) | 0 (0.00) | — | — | $\chi^2(1) = 2.98$, $p = .085$ |
| Other adverse events, for example, setbacks in the search for a therapy place, unwanted conflicts, stress | 5 (8.62) | 4.33 (0.82) | 2.50 (1.76) | 18 (32.14) | 3.93 (0.90) | 1.32 (0.82) | $\chi^2(1) = 9.06$, $p = .003$ |
| Adverse events per person, $M$ (*SD*) | 1.02 (1.10) | 2.78 (0.88) | 2.00 (1.17) | 1.55 (1.45) | 3.09 (0.86) | 1.74 (0.90) | $t(102.51) = 2.22$, $p = .029$ |

*Note*. AE = adverse events; TAU = treatment as usual; OIC = optimized informed consent; T1 = postassessment; T2 = 2-week follow-up; T3 = 3-month follow-up.

[a] The severity of each event was rated by the interviewer (T1) or the participant (T2, T3), if the occurrence of the adverse event was reported. The severity was rated using a 5-point Likert scale (1–5) with higher scores indicating greater severity. [b] The potential causal relationship to the study participation of each event was rated by the interviewer (T1) or the participant (T2, T3), if the occurrence of the adverse event was reported. The causal relationship was rated using a 5-point Likert scale (1–5) with higher scores indicating a more likely association with study participation.

(T2; $p = .492$) and 3 months later (T3; $p = .180$). No statistically significant group differences were found in the occurrence of *serious adverse events* at T1 and follow-ups. The mean score of all predefined adverse events was statistically significantly higher in TAU compared to OIC ($p = .029$) at T3, but not at T1 and T2. Additional adverse events occurred statistically significantly more often in the TAU ($n = 18$) than in the OIC ($n = 5$) group at T3, but not at T1 and T2. Intervention-related adverse effects were rarely reported (Supplemental eTable 3).

## Additional Analyses

Results of exploratory subscale analyses on the Treatment Expectation Questionnaire revealed a significant positive impact of the OIC on participants' expectations regarding treatment benefit, impact, process, and behavioral control and no significant group differences in adverse events and negative impact at T2 (Supplemental eTable 4). All Decisional Conflict Scale subscale scores were found to be significantly lower at T2 for OIC compared to TAU (Supplemental eTable 4). The intervention effects were robust regarding two sensitivity analyses: Per-protocol analyses and analyses with sociodemographic and clinical covariates confirmed the results of the intention-to-treat analyses (Supplemental eTables 5–7). Except for capacity to consent to treatment and autonomous treatment motivation, there was no evidence of systematic bias through differences between study psychologists (Supplemental eTable 8).

# Discussion

This randomized clinical trial of 122 adult individuals with mental disorders in Germany found significant positive effects of an OIC consultation on treatment expectations, motivation, adherence intention, knowledge about psychotherapy, decisional conflict, and capacity to consent to treatment. Adverse events with a possible relationship to intervention were rarely reported.

To our knowledge, this is the first experimental investigation of informed consent procedures for psychotherapy. The OIC was developed in line with the latest empirical evidence from expectation research (Evers et al., 2018; Rief, 2021) and integrates clinical, legal, and ethical functions. We chose an extensive and commonly used information brochure about psychotherapy to provide on-demand baseline information to all study participants. Fostering external validity, we included individuals with an indication for psychotherapy under real-world conditions using structured diagnostic interviews. This study tested the beneficial effects of a 35-min OIC over and above the effects on an on-demand information brochure. Most participants in both groups had engaged with the information brochure as TAU. The active components of the OIC include receiving verbal treatment information and discussing individual treatment expectations via shared decision making in an empathic practitioner–patient relationship. Nevertheless, future studies with different control groups are needed to determine which specific OIC procedures and/or information cause the positive effects of the OIC. Due to lack of validated measures, self-developed items were used for some assessments. The planned accessor blinding for the outcome capacity to consent to treatment could not be maintained for feasibility reasons (i.e., participants revealing information that indicated group allocation). Exploratory secondary outcome analyses should be interpreted with caution. Since most participants were recruited through social media, replication of this approach and extension to an offline context while balancing sociodemographic factors such as the education level is warranted to check for generalizability. In terms of ecological validity, it might be assumed that participants recruited by the cooperating outpatient clinics may have had more positive treatment expectations and higher treatment motivation because they had already actively sought a treatment service.

In line with previous findings from psychotherapy research and medical fields (Constantino et al., 2018; Rief et al., 2017; Shedden-Mora et al., 2020), our results indicate that expectation management functionally enhances patients' expectation and thus might also improve treatment efficacy. Consistent with the latest Cochrane review on decision aids (Stacey et al., 2017), patients receiving OIC seem to be individually supported in their decision-making process. Compared to other studies investigating singular strategies for optimizing treatment expectations and decision-making outcomes, effect sizes are large (Heisig et al., 2015; Shedden-Mora et al., 2020).

The OICs' mechanisms of action and their differential impact should be disentangled. Future research could also consider alternative hypotheses about mechanisms, such as the OIC might be therapeutically beneficial because it positively influences the treatment plan according to the needs of individual patients. As this trial investigated informed consent rather as a one-time event before psychotherapy than an ongoing process (Pomerantz, 2005), longitudinal studies might contribute to understanding the impact of informed consent before and during psychotherapy. The newly developed OIC might be further individualized and improved by considering disease-specific aspects, symptom severity, and patients' personality traits (Kube et al., 2018). Future studies should clarify whether optimized expectation and decision making through OIC effectively translate to better treatment outcomes.

This trial provides evidence for the feasibility of ethical informed consent for psychotherapy. Conveying transparent information about potential risks and side effects of psychotherapy might have temporarily increased awareness thereof and, in few cases, also induced short-term nocebo effects. However, OICs beneficial impact on therapy- and decision-related outcomes seem to outweigh adverse effects. In addition to the expected positive impact on treatment efficacy, the OIC could also have substantial ethical benefits in terms of supporting patient autonomy. If future results confirm these preliminary data, the informed consent procedure will gain clinical importance. During trial sessions prior to psychotherapy, psychotherapists could routinely implement the OIC as a practical guide to obtain informed consent, considering legal, ethical, and clinical aspects simultaneously. The OIC can be easily self-taught via freely available manual and adapted to differing settings and health care systems, with broad potential fields of application. Psychotherapists can use the OIC irrespective of the psychotherapeutic approach and context (on- or offline). The OIC might be an easily accessible and low-threshold decisional device that facilitates access to indicated treatments and improves the efficient use of available support options. Consequently, the OIC might be implemented at an earlier stage, for example, in counseling centers and online counseling for remote areas. Waiting times for psychotherapy might be reduced by providing interested parties

with better information about their treatment options in advance. In trainings, psychotherapists should be trained about potential ethical conflicts (i.e., weighing the ethical principles of nonmaleficence and respect for autonomy) and how to solve them by applying techniques of expectation management, contextualization, framing, and shared decision making.

## Conclusion

A one-session OIC was helpful in improving treatment expectations and decision making among patients with mental disorders in Germany. OIC appears to specifically reinforce positive expectations about treatment benefits and positive impact while not influencing potential negative treatment expectations. The OIC might contribute to implement legal and ethical requirements of informed consent in clinical practice while realizing its clinical potential.

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