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Integrative-interpersonal dynamic therapy for poststroke depression (INID): study protocol of a randomised controlled pilot trial

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ABSTRACT

Introduction Depression is the most frequent psychiatric disorder following stroke, affecting about one-third of stroke survivors. Patients experience poorer recovery, lower quality of life and higher mortality compared with stroke survivors without depression. Despite these well-known malign consequences, poststroke depression (PSD) is regarded underdiagnosed and undertreated. Evidence of beneficial effects of psychotherapy to treat PSD remains scarce and inconclusive and is limited by heterogeneity in design, content and timing of the intervention. This pilot study aims to assess the feasibility of a newly developed integrative-interpersonal dynamic PSD intervention in an outpatient setting and provide a first estimation of the potential effect size as basis for the sample size estimation for a subsequent definite trial.

Method and analysis Patients will be recruited from two German stroke units. After discharge from inpatient rehabilitation, depressed stroke survivors will be randomised to short-term psychotherapy (12 weeks, ≤16 sessions) or enhanced treatment as usual. The manualised psychotherapy integrates key features of the Unified Psychodynamic and Cognitive-Behavioural Unified Protocol for emotional disorders and was adapted for PSD. Primary endpoints are recruitment feasibility and treatment acceptability, defined as a recruitment rate of ≥20% for eligible patients consenting to randomisation and ≥70% completion-rate of patients participating in the treatment condition. A preliminary estimation of the treatment effect based on the mean difference in Patient Health Questionnaire-9 (PHQ-9) scores between intervention and control group six months poststroke is calculated. Secondary endpoints include changes in depression (PHQ-9/Hamilton Depression Scale) and anxiety (Generalised Anxiety Disorder 7) of all participants across all follow-ups during the first year poststroke.

Ethics and dissemination The INID pilot study received full ethical approval (S-321/2019; 2022-2286_1). Trial results will be published in a peer-reviewed journal in the first half of 2025. One-year follow-ups are planned to be carried out until summer 2025.

Trial registration number DRKS00030378.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This pilot study aims to provide a high-quality design to assess the feasibility and acceptability of a newly developed short-term intervention for stroke survivors suffering from poststroke depression.
⇒ Key aspects are the use of established manualised modules from psychodynamic and cognitive-behavioural psychotherapy, regular training and supervision of therapists, and an evidence-derived timing of the planned intervention.
⇒ Limitations are the unknown feasibility of recruitment rate and acceptability of the treatment modules, which have not yet been tested in this patient group.

INTRODUCTION

Depression is the most frequent psychiatric condition after stroke, affecting about one in three stroke survivors.[1–3] Poststroke depression (PSD) occurs most frequently during the first two years after stroke, with a tendency of peaking prevalence about six months after stroke,[4–7] when stroke survivors usually have returned home after inpatient rehabilitation and must readapt to their lives in their familiar environment. Depressed stroke survivors experience malign long-term consequences including poorer functional outcomes, longer hospitalisation, lower quality of life as well as higher mortality and reinfarction rates compared with stroke survivors without depression.[8–11] Moreover, stroke recovery may also be hampered by depressed stroke survivors' tendency to retreat from social participation.[12] Lastly, the burden of PSD also affects spousal and significant relationships.[13 14]

Despite these well-known negative consequences, PSD is regarded as both underdiagnosed and undertreated.[4 15 16] When PSD is diagnosed, less than 50% of depressed stroke

survivors receive antidepressant drug treatment, and less than 10% receive psychotherapy treatment.[17–19] This striking gap is exacerbated by missing treatment guidelines and scarce evidence for standardised psychotherapy treatments for PSD.[11] Moreover, psychotherapists might be reluctant to treat PSD due to an uncertainty how to address stroke-specific challenges, handle medication and often complex comorbid somatic symptoms.[17 20] Taken together, evidence-based, effective and standardised psychotherapeutic interventions are crucial to address the need of adequate treatment for the growing number of stroke survivors experiencing PSD. Moreover, treatment strategies for PSD should address the time-sensitive prevalence after stroke[6 11 21] and bridge the crucial gap between inpatient rehabilitation and the difficult reintegration in survivors' familiar environment[22] after discharge.

Interventions aiming at the treatment of PSD can be broadly grouped into two categories: pharmacological and non-pharmacological treatments. Recent meta-analytical evidence showed that antidepressant medication is by far the most frequent treatment strategy.[18 19 23] Pharmacological interventions using antidepressants mainly include selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, monoamine oxidase inhibitors and tricyclic antidepressants and are associated with greater reduction of both prevalence and levels of PSD compared with control treatments.[19 23] However, pharmacological interventions were also found to increase the risk of bone fractures and adverse central nervous system and gastrointestinal effects.[19 24 25]

Regarding non-pharmacological treatments of PSD, psychological (talking) therapies must be differentiated from other treatments such as acupuncture,[26] or non-invasive brain stimulation.[27] Psychotherapy is recommended as first-line treatment for mild and moderate depression, and in combination with antidepressants for severe depression by the German National Treatment Guidelines for Unipolar depression[28] and is associated with lower relapse rates than (only) pharmacotherapy and control treatments.[29]

Studies focusing on prevention of PSD suggest that brief and low-threshold psychological interventions may decrease PSD prevalence after stroke.[30 31] However, these trials did not focus on treatments of stroke survivors with clinical depression levels and/or diagnosed PSD. Recent meta-analytical evidence on treatments focusing on clinical levels of PSD found that psychological interventions were associated with a reduction of both prevalence and levels of PSD compared with control treatments at the end of treatment, but not at follow-up.[19] Although all of these assessed interventions were required to be talking therapies,[19] interventions were characterised by substantial heterogeneity across studies ranging from one session of motivational interviewing via telephone[32] up to weekly psychotherapy sessions over the course of several months.[33] Psychological interventions were mostly compared with a control condition (eg, treatment as usual (TAU) or no treatment) and were mostly based on short-term cognitive behavioural,[33–37] supportive (psychosocial) counselling,[32 38–41] motivational interviewing[42 43] or problem solving.[44] One pilot trial examined the effect of additional interpersonal psychotherapy during inpatient rehabilitation[45] and another pilot trial examined a new treatment called ecosystem focused therapy.[46] Two of these trials allowed for parallel medication for some patients,[34 47] while another trial prescribed parallel medication for part of the sample[45] and two trials included pharmacotherapy for the full sample.[37 48] Moreover, the majority of trials did not include follow-up assessments[34 38 40 41 43 44 46 47] while other trials which included a single follow-up assessment between 1.5 and 20 months after stroke[32 35–37 39 42] while the time of the baseline assessment after stroke ranged from 1 to 52 weeks after stroke. Regarding the application of treatment, interventions were carried out by trained therapists (including, psychological assistants),[33–37 46] nurses[32 42 43] social workers[44] or trained staff from various professional backgrounds.[40] Only six studies reported if therapists had initial training or regular supervision.[33 35–37 43 46] These limitations might have contributed to the heterogeneity and current level of conclusiveness of evidence for psychotherapy.[19]

In summary, evidence of the efficacy of psychological treatment of PSD remains fragmented and is limited by substantial heterogeneity across studies regarding the type of treatment, duration, follow-up assessments, time after stroke, administrating personnel, training and supervision. Established recommendations for psychotherapy trials include not only an adequate therapy exposure (ie, duration and dosage), but also sufficient therapist qualification to guarantee an adequate level of clinical expertise.[11 19 49–51] Moreover, the previous trials further differed in setting (inpatient rehabilitation, outpatient, home visits, telephone and face-to-face setting), the use of manualised interventions and the inclusion of caregivers. Moreover, most previous studies did not have or report sufficient statistical power based on an adequate sample size. Thus, previous trials on psychological interventions for PSD might not allow to assess the full potential effect of a manualised, stroke-specific psychotherapy due to their brevity and specific design characteristics outlined above.

Finally, no previous trial has investigated the efficacy of a manualised integrated interpersonal psychotherapy, delivered by trained and supervised therapists drawing on psychodynamic and cognitive-behavioural principles which explicitly considers the dynamic prevalence during the first year after stroke.

DESIGN AND METHOD

Overall aim and general framework

The primary aim of the present multicentre pilot (the terms 'pilot' and 'feasibility' study will be used according to[52] where a pilot study is defined as a special case of the feasibility study: A pilot study carries out a feasibility study with the unique feature that the pilot

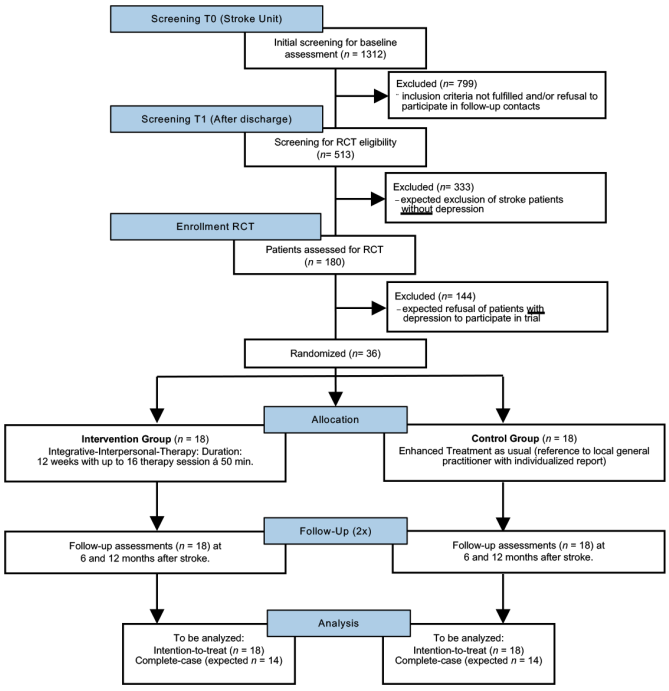

Figure 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram of patient recruitment and participation. Initial screening will take place at baseline (T0) on two stroke units, where stroke survivors will be invited to participate in the study and—given written informed consent—assessed for inclusion criteria (ie, occurrence of stroke and sufficient verbal and German language comprehension for study participation). Second screening will take place after discharge from inpatient rehabilitation. Participants will be randomised based on a cut-off for PSD (ie, a PHQ-9 score ≥11) to either an intervention or control-group (E-TAU) given their informed consent. Follow-up assessments will take place 6 (T2) and 12 (T3) months after stroke. E-TAU, enhanced treatment as usual; PHQ-9, Patient Health Questionnaire; PSD, poststroke depression; RCT, randomised controlled trial.

study will be carried with a design that mirrors the planed main trial on a smaller scale, that is, where the processes and procedures are planned to be applied in the main randomised controlled trial (RCT) if found feasible) study is to assess the feasibility of recruitment and treatment acceptability of a manualised intensive short-term psychotherapy. Moreover, the INID (Integrative-interpersonal dynamic therapy for post-stroke depression)-PILOT aims to provide a preliminary estimation of the effect size including confidence intervals of the new treatment to serve as a basis for sample size calculation for the planed main RCT. Recruitment is planned to be conducted from August 2023 to May 2024 at two German Stroke Units at the Dept. of Neurology at the University Hospital Düsseldorf and the University Hospital Heidelberg. The study was approved by the ethic committees of the Medical Faculties in Heidelberg (registry no: S-321/2019) and Düsseldorf (registry no: 2022-2286_1).

Recruitment and assessments

Figure 1 shows the Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the INID-PILOT: First, all stroke survivors will be screened for study eligibility at baseline (T0). Second, participants will be screened shortly after discharge from inpatient rehabilitation (T1) to assess RCT eligibility. After this second screening, patients with PSD will be randomised to either the control or intervention group. Note that this step (ie, the proportion of patients consenting to be randomised) will serve as a basis for the feasibility assessment (see below). Moreover, all participating patients screened at T1, will be assessed after 6 (T2) and 12 (T3) months regardless of their PSD levels to assess the influence and control for known risk factors and relevant outcomes (see below: secondary outcomes description). Randomised participants in the intervention group will have three additional assessments at beginning, mid and end of their 12-week intervention, which are planned to be carried out from November 2023 to November 2024 (ie, 12 weeks after the last patient was discharged from inpatient rehabilitation).

Feasibility and acceptability hypotheses

The planned psychotherapy intervention will take place at two university hospital departments and will be conducted after patients discharge from inpatient rehabilitation (T1). Given stroke survivors transition during this period,[6 22] it is unclear—and thus necessary to assess—how many patients will consent to randomisation and subsequent treatment and how many patients discontinue treatment participation. Based on available data from other PSD clinical trials,[36 43 44] we derived conservative thresholds for the feasibility of the recruitment rate and acceptability of the treatment in terms of treatment participation. The main aim of this pilot study is to assess the feasibility and acceptability of the study protocol: As primary outcome we define a rate of ≥20% for RCT eligible stroke survivors with clinical levels of depression at T1 consenting to randomisation as feasible. Acceptability is defined as ≥70% of randomised patients participation in ≥66% of therapy sessions, measured at the end of treatment.

Participants and selection criteria

Participants are patients admitted to the Stroke Unit at the Department of Neurology at the University Hospital Düsseldorf or the University Hospital Heidelberg. Screening will take place during the first week of admittance where stroke survivors will be invited to participate in the INID-PILOT. Participation will depend on participants' written informed consent (see online supplemental ESM1) and the following criteria:

Inclusion criteria at T0: Diagnosed occurrence of ischaemic stroke (International Classification of Diseases (ICD) -Code: I.63) or intracerebral haemorrhage (I.61) in patients admitted to the two Stroke Units. Sufficient verbal comprehension at baseline (T0) as defined by a sum of ≥6 points of the shortened Aphasie-Schnell-Test

(aphasia (AST)),[53 54] signifying a comparatively low threshold for patients to be included.[53] Sufficient German language comprehension for questionnaire completion and participation in psychotherapy, assessed at baseline (T0).

Inclusion criteria for randomisation at T1: Depression (ie, a Patient Health Questionnaire-9 (PHQ-9) score ≥11) after discharge from inpatient rehabilitation. This cut-off is based on meta-analytical evidence for diagnosing PSD, showing that it offers an optimal trade-off between sensitivity and specificity across several settings and was therefore set over the PHQ-9 manual-recommended (non-stroke-specific) threshold of 10.[55–57] The rationale for choosing this cut-off is to recruit a sample with high enough levels of PSD (in terms of PHQ-9 scores) to expect a clinically relevant effect, yet low enough to include a representative PSD sample.

Exclusion criteria: Patients with diagnosed transitory ischaemic attack (ICD-Code G.45), due to limited comparability between the impact of transitory complications and potentially chronic consequences of stroke on patients' affective well-being. Patients with severe intracerebral haemorrhage, requiring neurosurgical treatment shortly after stroke.

Note that, applying international recommendations,[11 58] we minimised the number of exclusion criteria to allow a representative range of stroke survivors with PSD to be eligible.

Randomisation

Participating patients will be randomised to either the treatment conditions or E-TAU at T1, which will take place shortly after discharge from inpatient rehabilitation (cf. figure 1). Randomisation will be conducted using R package blockrand,[59] ensuring transparent and chance-based group allocation of all eligible participants. Group randomisation will be stratified based on severity of depressive symptoms (PHQ-9 ≥15, after discharge from inpatient rehabilitation) and stroke severity (National Institute of Health Stroke Scale (NIHSS) ≥6 (ie, threshold between minor and moderate stroke) at baseline) to increase comparability. To avoid predictable patterns in randomisation, block sizes will be permutated with sizes of 2 or 4.[59]

Procedure after initial screening

After baseline screening at the university departments of neurology (T0), eligible study participants will be contacted shortly after discharge from inpatient rehabilitation, approximately 3 months after stroke (T1). Randomisation will take place after the T1 screening with patients above the defined cut-off for depression (PHQ-9 score ≥11) given their informed consent. To avoid systematic bias, follow-up interviews will be carried out by blinded interviewers at Kassel University, (ie, psychology B.Sc. and/or M.Sc. students who receive clinical training). In the intervention group, participants will be additionally assessed at the beginning and end of treatment, and every fifth therapy session (cf. table 1).

Treatment

The proposed manualised treatment integrates key aspects of psychodynamic and cognitive-behavioural psychotherapy for depressed stroke patients. The focus is on the interpersonal dynamic after stroke using the psychodynamic Core-Conflictual-Relationship-Theme (CCRT)[60] in addition to structured elements for behavioural activation and fostering of patients' agency. Furthermore, patients' family members are routinely offered support and can be included in the treatment. Study treatment will consist of manualised integrative-interpersonal dynamic therapy over a period of 12 weeks. Patients will receive two diagnostic evaluations (see module 1) and up to 16 individual psychotherapy sessions. The treatment will be conducted as individual outpatient therapy. Exceptions to the individual therapy setting are two preplanned sessions, where patients are invited to bring their partner and/or other family members to the therapy (module 2 and 6). In addition, two group sessions for family members are offered during each patient's individual treatment (module 8) to provide psychoeducation and connect caregivers among themselves. In case of immobility of patients, the therapist can also visit at home and conduct therapy sessions there.

The treatment is manualised and integrates key features of the Unified Psychodynamic Protocol (UPP) for depressive disorders[61] as well as the Cognitive-Behavioural Unified Protocol (CB-UP) for emotional disorders.[62] Consistent with the recommendations of both unified protocols, the manual is organised in treatment modules and includes elements on treatment motivation, setting of treatment goals and psychoeducation as well as a relapse prevention module. Following the UPP, the therapy focuses on raising patients' self-understanding of their CCRT[60] and the connection between the interpersonal dynamics, the experience of stroke and depressive symptoms. In accordance with the CB-UP, the therapy includes tools and exercises aimed at raising emotional awareness, reducing behavioural avoidance and facilitating cognitive reappraisal. A specific focus on supportive interventions is intended to facilitate a positive therapeutic alliance. The modules are: (1) diagnostics using (semi)structured interviews (two sessions), (2) psychoeducation and treatment rationale (two therapy sessions), (3) motivation and individual treatment goals (two therapy sessions), (4) emotional awareness (two therapy sessions), (5) maladaptive interpersonal pattern in everyday life (six therapy sessions), (6) termination and relapse prevention (four therapy sessions), (7) supportive alliance interventions (across entire treatment) and an optional module (8) for family members and caregivers (invitation to two patient sessions and two separate and specific sessions for caregivers).

Control condition

Patients randomised to the control condition will receive enhanced TAU (E-TAU). E-TAU consists of the standard

Table 1 Overview of measures, type of rating, source and measurement occasions of the INID pilot trial

	Type/source	Measurement occasion
Measures for all participants		
Structured Clinical Interview for DSM-5 (SCID I)	Observer based	T0, T1*, T2*, T3*
Patient Health Questionnaire (PHQ-9)	Self-assessment	T0, T1, T2, T3
Hamilton Depression Scale (HAMD-D)	Observer based	T0, T1, T2, T3
Generalised Anxiety Disorder 7 (GAD-7)	Self-assessment	T0, T1, T2, T3
Social Support Questionnaire (F-SozU-K6)	Self-assessment	T0, T1, T2, T3
European Quality of Life 5 Dimensions (EQ-5D)	Self-assessment	T0, T1, T2, T3
OPD Structure Questionnaire Short Form (OPD-SQS)	Self-assessment	T0, T1, T2, T3
Modified Ranking Scale (mRS)	Observer based	T0, T1, T2, T3
Self-Compassion Scale-Short Form	Self-assessment	T0, T1, T2, T3
Montreal Cognitive Assessment (MoCA)	Observer based	T0
Barthel-Index (BI)	Observer based	T0
Mod. National Inst. of Health Stroke Scale	Observer based	T0
Aphasie-Schnell-Test (AST)	Observer based	T0
Post-Stroke-Depression Risk Scale (PoStDeRiS)	Observer based	T0
Signs of Depression Scale (SODS)	Observer based	T0
Additional measures for the intervention group		
Operationalised Psychodynamic Diagnostic (OPD-2) Interview	Observer based	DS1
Experience in Close Relationship-Revised (ECR-R)	Self-assessment	DS1, EOT
OPD Structure Questionnaire - Short (OPD-SQS)	Self-assessment	DS1, EOT
Patient Health Questionnaire (PHQ-9)	Self-assessment	Every fifth TS until EOT
Working Alliance Inventory (WAI-SR) (Patient and therapist)	Self-assessment	Every fifth TS until EOT

T0=baseline assessment during the first week after stroke; T1=after discharge from inpatient rehabilitation; T2=6 months after stroke; T3=12 months after stroke; DS prior to treatment; TS (up to 16 over the 12-week long treatment); detailed instrument description is provided below.
*During follow-up, SCID-I interviews will be conducted fully for the intervention group and the depression part for all participants.
DS, diagnostic session; DSM, Diagnostic and Statistical Manual of Mental Disorders; EOT, end of treatment; TS, therapy session.

referral of patients after regular discharge from inpatient rehabilitation, mostly to their general practitioner (GP). As enhancement, stroke survivors will receive their individual results of the psychological study assessment (table 1) to complement their standard discharge report. Patients are encouraged to share the results of their psychological assessments with their GP and initiate treatment if indicated. All treatments (antidepressant medication, psychotherapy, speech therapist, etc) initiated by the patient or their GP will be recorded throughout follow-up assessments. In addition, E-TAU participants will receive contact information for local self-help organisations.

Therapists

Therapists hold a PhD, an M.D. or a master's degree in psychology or equivalent (eg, Dipl.-Psych.). They are required to have at least 2 years of clinical experience. Furthermore, previous outpatient psychotherapy of depressed patients is a prerequisite to be included as therapist. Therapists will receive specific training based on the treatment manual prior to the start of the trial. In addition, they will participate in biweekly group supervision throughout the entire study period. During supervision, video recordings will be used to continuously monitor adherence throughout the study.

Medication

Antidepressant medication will be documented at all measurement occasions using half-structured interviews. Because a discontinuation of antidepressant medication shortly after its start during an ongoing depressive episode is potentially harmful and may lead to further symptom aggravation,[63] existing antidepressant medication will not be changed or conditioned for randomised patients, but recorded and used as a covariate (see the 'Statistical analysis' section). With this procedure, the proportion of (pre)medicated patients and changes in regiments[17] can be estimated for a subsequent confirmatory definite trial.

Patient and public involvement

Patient involvement was secured throughout trial planning by involving key local self-help organisations and integrating their feedback. For example, the specific module for family members and caregivers was newly designed and included based on patient representatives' feedback as well as the reference of patients in the control

condition (E-TAU) to their respective local self-help organisation after T1 screening.

Outcome measures

Table 1 lists all outcome measures throughout the INID-PILOT trial.

The Patient Health Questionnaire (PHQ-9) is a self-report instrument for depression according to Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria.[56] Psychometric evaluation showed excellent discrimination between depressed and non-depressed stroke patients (minor and major depression) with specificity of 0.89 and sensitivity of 0.89 for the cut-off of ≥11.[57] The PHQ-9 will be the primary outcome measure in this trial.

The Structured Clinical Interview for DSM-5 clinical version represents a semistructured clinical interview to assess and diagnose Axis 1 mental disorders according to DSM-5 criteria.[64] Psychometric evaluation showed satisfactory inter-rater and retest reliability.[65]

The Hamilton Depression Scale (HAMD-D) is a 21-item standard observer-rated instrument to assess the severity of depression.[66] Psychometric evaluation showed high construct validity and acceptable discrimination between depressed and non-depressed stroke patients with specificity of 0.94 and sensitivity of 0.54 for the recommended cut-off of ≥10.[67]

The Generalised Anxiety Disorder 7 (GAD-7) allows the brief self-assessment of anxiety symptoms based on DSM criteria.[68] The seven-item questionnaire is used in primary care and shows favourable psychometric evaluation with specificity of 0.82 and sensitivity of 0.89 for the standard cut-off of ≥10.

The Social Support Questionnaire (F-SozU-K6) allows the brief self-assessment of perceived social support. The six-item short version captures patients' perceived social support on a 5-point Likert-Scale. Psychometric evaluation showed excellent characteristics.[69]

The Questionnaire for European Quality of Life 5 Dimensions (EQ-5D) assesses five dimensions of perceived problems in five health domains on a 5-point Likert-scale, next to an overall assessment on a 0–100 Visual Analogue Scale. The EQ-5D is validated in the general population and patient samples including cardiovascular disease and showed satisfactory reliability and validity.[70]

Patients' medication (drug class, dosage and regimen) after acute and inpatient rehabilitation will be obtained from medical files and/or discharge reports or semistructured interviews during the telephone follow-ups.

The Montreal Cognitive Assessment (MoCA) is a brief screening instrument for mild cognitive impairments which was developed to address ceiling effects of comparable measures.[71] Validation in patients who had a stroke showed favourable psychometric properties.[72]

The Barthel-Index (BI) allows standard assessment of functional independence in terms of patients' ability to perform activities of daily living.[73] Scores range from 0 (complete dependence/disability) to 100 (complete independence). The BI is a routinely used and represents the most consistently found predictor for PSD.[11 74]

The modified National Institute of Health Stroke Scale (mNIHSS) allows a graded assessment of patients' stroke severity in terms of neurological deficits[75] including motoric/sensory impairment, level of consciousness, visual field/movement, language and neglect. Psychometric evaluation showed favourable properties in various clinical settings.

The German version of the AST (Aphasia Quick Test) was used in a shortened form according to,[54] which is especially suited the acute setting.[53] The AST captures the ability to comprehend and execute verbal commands. In our study, the cut-off of ≥6 was used for all ages groups as a relatively low threshold for inclusion.[15 54]

The Post-Stroke Depression Risk Scale is a short observer-based assessment, which allows accurate identification risk patients for PSD.[19] It consists of three items (history of depression, PHQ-2 Items and BI) and was developed for assessments during acute care.[19]

The Signs of Depression Scale (SODS) is one of the few non-language based PSD screening instruments,[76] which was developed for acute care settings. It consists of six items answered on a yes/no scale and can be administered by staff or family members.

The modified Rankin Scale (mRS) represents a standard observer-based measure of functional outcome[77] and is assessed on a 7-point scale ranging from 0 (no symptoms at all) to 6 (death). Psychometric evidence showed excellent reliability and satisfactory validity.[78]

The Self-compassion Scale-Short Form[79] is a self-report measure of self-compassion as the ability to hold one's feelings of suffering with a sense of warmth, connection and concern. It evaluates how often certain actions are used in difficult times by a 5-point scale ranging from 1 (almost never) to 5 (almost always). Psychometric evidence demonstrated good reliability and validity.[79]

The Operationalised Psychodynamic Diagnostic (OPD-2) assesses patients relationship patterns, conflict and structure using a semistructured clinical interview.[80 81] The OPD-2 interview shows satisfactory psychometric properties and represents a standard instrument for psychodynamic diagnostics.[81]

The Experience in Close Relationships-Revised (ECR-R) is a brief self-assessment capturing individual differences in attachment style.[82] This eight-item version assesses patients' perception of current and past relationships on a 7-point Likert scale. Psychometric evaluation showed acceptable model fit.

The short form of the OPD Structure Questionnaire (OPD-SQS) is a 12-item self-assessment capturing three dimensions (self-perception, contact organisation and relationship model and of structural deficits). Psychometric evaluation showed adequate model fit, reliability and validity in therapeutic contexts.[83]

Working Alliance will be assessed using the revised short-form of the Working Alliance Inventory (WAI-SR).[84] This 12-item self-report allows a reliable and brief assessment of Bordin's[85] three-factor model (bond, task, goals). The WAI-SR can be used for patients and therapists and shows excellent psychometric properties.[86]

Statistical analysis

Feasibility will be assessed by calculating recruitment rates of RTC eligible patients at T1 (see the ' Feasibility and acceptability hypotheses' section). For the preliminary estimation of effect size and sample size calculation, the mean difference in PHQ-9 scores between the intervention and control group at T2 (6 months after stroke) will be used. Effect size calculation will be standardised by using the pooled, bias-corrected (for n<50) SD between the intervention and control group.

As secondary outcome, changes in depression (PHQ-9/HAMD-D) and anxiety (GAD-7) across all follow-ups will be tested using (multivariate) analysis of variances (ANOVA) with repeated measurements. These analyses also encompasses all participants, regardless of randomisation and levels of PSD at T1. Relevant measures, which are known predictors of PSD (eg, BI, MoCA, mNIHSS, F-SozU-K6, QoL, early depressive symptoms (HAMD-D/SODS)) are assessed as described in table 1 to be included as covariates for the analysis of the secondary outcomes.

Sample size estimation: For this pilot study, we aim to recruit n=18 patients for each group, the intervention and control group (E-TAU). This sample size calculation is based on CI approach, following the CONSORT recommendations for pilot studies.[52 87 88] The CI approach uses the anticipated larger RCT to estimate the pilot trial's sample size.[87] Specifically, the approach yields a pilot sample size where the expected CI excludes a clinically significant threshold given that the treatment has no (zero) significant effect. Thus, if the CI of the treatment effect in the pilot study reaches (or overcomes) the threshold, it is recommended to move forward with the anticipated main study.[87] In more statistical terms, the sample size calculation is based on a one-sided 80 or 90% CI, where the upper limit excludes a predefined threshold of clinical significance. In this pilot study, this threshold was defined as a medium standardised effect size of d=0.50 for the primary outcome (ie, PHQ-9 at 6-month follow-up). This effect size is drawn from mean effect sizes of other psychotherapies (for a recent meta-analysis, see Leichsenring *et al*[89]) and corresponds to a PHQ-9 reduction of about 3 points when considering the SD of the PHQ-9 in stroke populations.[90 91] For the sample size estimation, a 90% (ie, more conservative than 80%) CI was chosen, yielding a required sample size of n=14 for each group.[87] Notably, this does not account for study drop-out, which was assumed to be about 30%,[36 43 44] resulting in our final sample size of n=18 for each group. Intention-to-treat analysis will be carried out for the effect size calculation.[92]

ETHICS AND DISSEMINATION

The INID pilot study received ethical approval from both recruitment locations (University Hospital Heidelberg: Reg-Nr.: S-321/2019) and the Heinrich-Heine-University Düsseldorf (Reg-Nr.: 2022-2286_1) and complies with the Declaration of Helsinki.[64] Adverse events are not expected throughout the trial. Patients in the intervention group will be informed about potential side effects[93] of psychotherapy, in compliance with German professional regulations. Data management was evaluated within the ethics approval process according to the General Data Protection Regulation. Recruitment is planned to commence in August 2023 and last 9 months until May 2024. The intervention is planned to start in November 2023 (ie, about 3 months after the start of recruitment) and last until November 2024 (ie, about 6 months after the last patient was recruited). Publication of trial results is expected during the first half of 2025 after recruitment and subsequent treatment termination. Follow-ups are planned to be carried out until May 2025 (ie, 1 year after the last patient was recruited). The INID pilot study is pre-registered at the German register for clinical studies (Deutsches Register Klinischer Studien: Reg-Nr. DRKS00030378).

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Contributors UD and MV conceptualised the study design and the new treatment, BW consulted on the methodology. MV wrote the original draft of the manuscript. UD, HS, SGM, BW, KW, JPB, RS, LB and SM contributed to reviewing and editing. Additionally, BW edited the method section. All authors contributed to further revisions and have read and approved the final manuscript.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

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Titel der Studie: Emotionale Folgen nach Schlaganfall: Integrativ- Interpersonelle Therapie bei Depression nach Schlaganfall (INID-PILOT)

Hiermit erkläre ich, dass ich über das Wesen, die Bedeutung und die Tragweite der Studie sowie die sich für mich daraus ergebenden Anforderungen aufgeklärt worden bin. Ich hatte ausreichend Zeit, Fragen zu stellen und mich zu entscheiden. Aufgetretene Fragen wurden mir von dem Studienmitarbeiter oder der Studienmitarbeiterin verständlich beantwortet. Ich bestätige, dass ich den Text der Patientenaufklärung und dieser Einwilligungserklärung gelesen und verstanden habe.

Zusatz Teilstudie 2:
Sollte bei mir *nach* der stationären Rehabilitation eine emotionale Belastung durch den Schlaganfall festgestellt werden, willige ich zusätzlich ein, an Studie zur psychotherapeutischen Behandlung teilzunehmen. Mir ist bekannt, dass in diesem Rahmen Videoaufzeichnungen von meiner Person in den Therapiesitzungen gemacht, gespeichert und pseudonymisiert ausgewertet werden.

☐ Ja, ich willige ein. ☐ Nein, ich willige nicht ein.

Datenschutz

Mir ist bekannt, dass bei dieser Studie personenbezogene Daten verarbeitet werden sollen. Die Verarbeitung der Daten erfolgt nach gesetzlichen Bestimmungen und setzt gemäß Art. 6 Abs. 1 lit. a der Datenschutz-Grundverordnung folgende Einwilligungserklärung voraus:

Ich wurde darüber aufgeklärt und stimme freiwillig zu, dass meine in der Studie erhobenen Daten, insbesondere Angaben über meine Gesundheit und emotionale Verfassung zu den in der Informationsschrift beschriebenen Zwecken in pseudonymisierter Form im Klinischen Institut für Psychosomatische Medizin aufgezeichnet, gespeichert, ausgewertet werden. Mir ist zudem bekannt, dass weitere Daten, insbesondere Angaben über meine Gesundheit und emotionale Verfassung durch das Psychologische Institut der Universität Kassel per Telefongespräch erhoben werden. Mit ist bekannt, dass die erhobenen Daten in pseudonymisierter Form zum Zwecke der Auswertung und Analyse an das Universitätsklinikum Heidelberg weitervermittelt werden. Weiterhin ist mir bekannt, dass im Rahmen der Teilstudie 2 Videoaufzeichnungen von den Therapiesitzungen gemacht werden, die aufgrund der Auswertungsmethode weder (direkt oder indirekt) anonymisiert oder pseudonymisiert werden können. Die Ergebnisse der Auswertungen werden allerdings nur pseudonymisiert gespeichert werden. Dritte erhalten keinen Einblick in unverschlüsselte personenbezogene Unterlagen. Bei der Veröffentlichung von Ergebnissen der Studie wird mein Name ebenfalls nicht genannt. Die personenbezogenen Daten werden anonymisiert, sobald dies nach dem Forschungszweck möglich ist. Die Videodateien werden nach Abschluss der Datenauswertungen und spätestens 10 Jahre nach Abschluss der Studie vernichtet.

Mir ist bekannt, dass diese Einwilligung jederzeit schriftlich oder mündlich ohne Angabe von Gründen widerrufen werden kann, ohne dass mir dadurch Nachteile entstehen. Die Rechtmäßigkeit der bis zum Widerruf erfolgten Datenverarbeitung wird davon nicht berührt.

In diesem Fall kann ich entscheiden, ob die von mir erhobenen Daten gelöscht werden sollen oder weiterhin für die Zwecke der Studie verwendet werden dürfen.

Über den o.g. Studienzweck im Rahmen der INID-PILOT Studie hinaus werden die Daten ausschließlich zu Zwecken im Forschungsbereich „Emotionale Folgen nach Schlaganfall“ verwendet.

Ich möchte die Verwendung meiner Daten für andere/künftige Forschungszwecke wie folgt eingrenzen:
(Bitte ankreuzen)

☐ einer uneingeschränkten Verwendung meiner pseudonymisierten Daten zu Forschungszwecken über die INID-PILOT Studie hinaus **stimme ich zu**

☐ einer uneingeschränkten Verwendung meiner pseudonymisierten Daten zu Forschungszwecken über die INID-PILOT Studie hinaus **stimme ich nicht zu**

☐ Die Versicherungsunterlagen zur Wegeunfallversicherung wurden mir ausgehändigt

_____ _____

Ort, Datum Name, Vorname des Teilnehmenden (in Druckbuchstaben)

_____

Unterschrift des Teilnehmenden

Aufklärende Person

Der Teilnehmende wurde von mir im Rahmen eines Gesprächs über das Ziel und den Ablauf der Studie sowie über die Risiken aufgeklärt. Ein Exemplar der Informationsschrift und der Einwilligungserklärung [ggf. der Versicherungsbestätigung und Allgemeinen Versicherungsbedingungen] habe ich dem Teilnehmenden ausgehändigt.

_____ _____

Ort, Datum Name, Vorname aufklärende Person (in Druckbuchstaben)

_____

Unterschrift der aufklärenden Person

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Institut für Psychosoziale Prävention
Prof. Dr. phil. Svenja Taubner

Version 2 vom 23.04.2020

Einwilligung zur Teilnahme an der Studie
„Emotionale Folgen nach Schlaganfall“ (INID-PILOT)

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Datenschutz
Mir ist bekannt, dass bei dieser Studie personenbezogene Daten verarbeitet werden sollen. Die Verarbeitung der Daten erfolgt nach gesetzlichen Bestimmungen und setzt gemäß Art. 6 Abs. 1 lit. a der Datenschutz-Grundverordnung folgende Einwilligungserklärung voraus:

Ich wurde darüber aufgeklärt und stimme freiwillig zu, dass meine in der Studie erhobenen Daten, insbesondere Angaben über meine Gesundheit und emotionale Verfassung zu den in der Informationsschrift beschriebenen Zwecken in pseudonymisierter Form im Klinischen Institut für Psychosomatische Medizin aufgezeichnet, gespeichert, ausgewertet werden. Mir ist zudem bekannt, dass weitere Daten, insbesondere Angaben über meine Gesundheit und emotionale Verfassung durch das Psychologische Institut der Universität Kassel per Telefongespräch erhoben werden. Mir ist bekannt, dass die erhobenen Daten in pseudonymisierter Form zum Zwecke der Auswertung und Analyse an das Universitätsklinikum Düsseldorf weitervermittelt werden. Weiterhin ist mir bekannt, dass im Rahmen der Teilstudie 2 Videoaufzeichnungen von den Therapiesitzungen gemacht werden, die aufgrund der Auswertungsmethode weder (direkt oder indirekt) anonymisiert oder pseudonymisiert werden können. Die Ergebnisse der Auswertungen werden allerdings nur pseudonymisiert gespeichert werden. Dritte erhalten keinen Einblick in unverschlüsselte personenbezogene Unterlagen. Bei der Veröffentlichung von Ergebnissen der Studie wird mein Name ebenfalls nicht genannt. Die personenbezogenen Daten werden anonymisiert, sobald dies nach dem Forschungszweck möglich ist. Die Videodateien werden nach Abschluss der Datenauswertungen und spätestens 10 Jahre nach Abschluss der Studie vernichtet.

UNIVERSITÄTS KLINIKUM HEIDELBERG

Klinik für Allgemeine Innere Medizin und Psychosomatik
Thibautstraße 4 | 69115 Heidelberg

Zentrum für Psychosoziale Medizin

Klinik für Allgemeine Psychiatrie
Prof. Dr. med. Sabine Herpertz

Klinik für Allgemeine Innere Medizin und Psychosomatik
Prof. Dr. med.
Hans-Christoph Friederich
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Klinik für Kinder- und Jugendpsychiatrie
Prof. Dr. med.-univ. Franz Resch

Institut für Medizinische Psychologie
Prof. Dr. phil. Beate Ditzen

Institut für Psychosoziale Prävention
Prof. Dr. phil. Svenja Taubner

Version 2 vom 23.04.2020

Mir ist bekannt, dass diese Einwilligung jederzeit schriftlich oder mündlich ohne Angabe von Gründen widerrufen werden kann, ohne dass mir dadurch Nachteile entstehen. Die Rechtmäßigkeit der bis zum Widerruf erfolgten Datenverarbeitung wird davon nicht berührt.

In diesem Fall kann ich entscheiden, ob die von mir erhobenen Daten gelöscht werden sollen oder weiterhin für die Zwecke der Studie verwendet werden dürfen.

Über den o.g. Studienzweck im Rahmen der INID-PILOT Studie hinaus werden die Daten ausschließlich zu Zwecken im Forschungsbereich „Emotionale Folgen nach Schlaganfall“ verwendet.

Ich möchte die Verwendung meiner Daten für andere/künftige Forschungszwecke wie folgt eingrenzen:
(Bitte ankreuzen)

☐ einer uneingeschränkten Verwendung meiner pseudonymisierten Daten zu Forschungszwecken über die INID-PILOT Studie hinaus **stimme ich zu**

☐ einer uneingeschränkten Verwendung meiner pseudonymisierten Daten zu Forschungszwecken über die INID-PILOT Studie hinaus **stimme ich nicht zu**

_____ _____

Ort, Datum Name, Vorname des Teilnehmenden (in Druckbuchstaben)

_____

Unterschrift des Teilnehmenden

Aufklärende Person

Der Teilnehmende wurde von mir im Rahmen eines Gesprächs über das Ziel und den Ablauf der Studie sowie über die Risiken aufgeklärt. Ein Exemplar der Informationsschrift und der Einwilligungserklärung [ggf. der Versicherungsbestätigung und Allgemeinen Versicherungsbedingungen] habe ich dem Teilnehmenden ausgehändigt.

_____ _____

Ort, Datum Name, Vorname aufklärende Person (in Druckbuchstaben)

_____

Unterschrift der aufklärenden Person

[1] Gemäß Art. 9 Abs. 1 DSGVO handelt es sich bei Gesundheitsdaten um personenbezogene Daten besonderer Kategorie in deren Verarbeitung der Studienteilnehmer ausdrücklich einwilligen muss. Gleiches gilt für Daten, aus denen die rassische und ethnische Herkunft, politische Meinungen, religiöse oder weltanschauliche Überzeugungen oder die Gewerkschaftszugehörigkeit hervorgehen, sowie für die Verarbeitung von genetischen Daten, biometrischen Daten zur eindeutigen Identifizierung einer natürlichen Person, Daten zum Sexualleben oder zur sexuellen Orientierung.

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