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The Efficacy of Brief Parent–Infant Psychotherapy for Treating Early Regulatory Disorders: A Randomized Controlled Trial

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Objective: Early regulatory disorders (ERD) place considerable strain on the parent–infant relationship and are associated with high parental distress. Brief (4-session) psychodynamic-based focused parent–infant psychotherapy (fPIP) treats ERD by strengthening the quality of the parent–infant relationship. This randomized controlled trial investigates the efficacy of fPIP for treating ERD compared to standard pediatric care (treatment as usual [TAU]).

Method: Participants were 154 mothers and infants from 4 to 15 months who met criteria for persistent excessive crying, sleeping disorders, feeding disorders, or regulation disorders of sensory processing and were randomly assigned to fPIP (n = 81) or TAU (n = 73). Assessments took place at baseline and at the end of treatment after 12 weeks. Primary outcomes were the infants' regulatory symptoms and remission rate. Secondary outcomes were parents' psychological distress, depression, parenting stress, maternal self-efficacy, parental reflective functioning, and observer-rated emotional availability.

Results: fPIP was superior to TAU in reducing infants' overall symptoms ($p = .004$, $\eta^2 = 0.05$, CI = 0.01–0.12), night-waking disorders ($p = .030$, odds ratio = 3.12, CI = 1.21–9.22), and mothers' psychological distress ($p = .000$, $\eta^2 = 0.08$, CI = 0.03–0.16) and depression ($p = .002$, $\eta^2 = 0.06$, CI = 0.02–0.13). There was a trend suggesting that fPIP led to increased maternal self-efficacy and parental reflective functioning.

Conclusion: Results underscore the efficacy of brief fPIP in significantly reducing symptoms in infants with ERD and their mothers. Generalizability is restricted to low psychosocial risk samples with highly distressed mothers and comorbid ERD with a predominance of night-waking disorders.

Clinical trial registration information: The Efficacy of a Brief Parent–Infant Psychotherapy for the Treatment of Early Regulatory Disorders: A Randomized Controlled Trial; https://www.drks.de/drks_web/; DRKS00005739.

Key words: parent–infant psychotherapy, early regulatory disorders, infant mental health, psychodynamic therapy, parenting interventions

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Infant sleeping, feeding, and sensory disorders are found in approximately 10.9% of the general population and are the most prevalent diagnoses found in children between 0 and 3 years of age.[1] These problems have been referred to as early regulatory disorders (ERD).[2,3] ERD place a considerable strain on the parent–infant relationship and are associated with parenting stress and burden,[1,3,4] which can increase the likelihood of children developing mental health problems later on.[5] A meta-analysis revealed a weighted mean effect of $\eta^2 = 0.04$ for the association between infant regulatory problems and behavioral and psychological problems in childhood.[6] The latter in turn predicted problems in adolescence.[7] Infants with ERD are in need of efficient interventions that decrease regulatory symptoms, decrease parental burden, and improve the parent–infant relationship.

Efficacy of Parent–Infant Interventions

Several meta-analyses on the efficacy of parent–child interventions reveal promising results for different populations,[8-10] yet only a minority of trials were specifically designed for treating parents of infants with ERD. Mihelic *et al.* included controlled studies for the improvement of parenting skills, and found a small effect of interventions based on the behavioral model on infants' sleeping behavior ($\eta^2 = 0.014$) but not on infants' crying behavior ($\eta^2 = 0.018$).[9] However, the meta-analysis was not restricted to clinical samples with ERD, and included low-risk populations.

Three randomized controlled trials (RCT) investigated the efficacy of parent–infant psychotherapy (PIP) in high-risk samples.[11-13] PIP is a dyadic intervention that aims to improve the parent–infant relationship and to promote

secure infant attachment. In one study, psychodynamic PIP provided by nurses in public health care was more effective compared to TAU in improving dyadic relationship quality, maternal sensitivity, and maternal depression.[11] Two of the studies compared the effect of psychodynamic-based PIP with an alternative PIP that focused mainly on parent–infant interaction. Robert-Tissot *et al.* found that both treatments led to similar results 1 week and 6 months after treatment: namely, infants' decreased symptoms and mothers' increased sensitivity and self-esteem.[12] Cohen *et al.* showed that both types of PIP reduced infants' problems, maternal intrusiveness, and parenting stress, and led to a higher sense of parenting competence.[13] The effects were maintained or improved at 6-month follow-up.[14] Although the effects of interaction-focused PIP yielded better short-term effects, follow-up data indicated that psychodynamic PIP led to similar improvements, albeit more slowly.

These studies show that PIPs focusing on the parent–infant relationship in high-risk samples are effective. However, the few trials conducted did not include infants with ERD exclusively. Moreover, these trials were limited by small sample size, weakly defined inclusion criteria in some studies, and no adherence testing. Finally, the high variability in length and frequency among different PIPs begs the question of whether brief PIP is effective in treating infants with ERD.

Focused PIP

Focused PIP (fPIP) is a manualized brief psychodynamic-based intervention for treating ERD.[15-17] The aim of fPIP is to strengthen the parent–infant relationship and to have a positive impact on infants' development. To do so, fPIP targets the mother's internal representation of her infant, which may be affected by her own attachment experiences, and explores links between this internal image and her current relationship with her child.

The treatment uses 2 main strategies. A supportive strategy is used when a parent exhibits a deficit in mentalizing capacity (ie, the ability to understand behavior in terms of mental states). Such deficits indicate that parents less likely benefit from psychodynamic interventions such as interpretation.[18] An expressive strategy is indicated when a parent exhibits average or superior mentalizing capacity, which enables a discussion of how the problems in the parent–infant relationship may be connected to an intrapsychic conflict. In both strategies, strengthening parents' ability to mentalize the child is thought to be key for change. The treatment seeks to connect representational and interactional levels of the parent−child relationship. Behavioral interventions targeting dysfunctional parent–infant interactions in addition to information on infant development and ERD are integrated. Finally, fPIP works with all relevant caretakers, and integrates a systemic lens in its model in terms of couple and family dynamics. A comprehensive introduction to fPIP and a clinical case description have been published previously.[19]

The Present Study

This study aims to investigate the efficacy of fPIP for the treatment of ERD as superior to the treatment usually provided by the family pediatrician, according to current health practices (treatment as usual [TAU]). Our hypothesis was that fPIP would be more effective in reducing infants' symptoms in the domains of sleeping, crying, and feeding, as measured by parental self-report and percentage change in remission from diagnosis. In addition, and in line with fPIP's aims, we expected fPIP to be more effective in reducing parents' psychological distress and depression, decreasing parenting stress, and increasing parental self-efficacy, parental reflective functioning, and emotional availability in the parent–infant interaction.

METHOD

Study Design

We used an RCT design with a parallel-group 2-arm comparison of fPIP versus TAU. Assessments took place at baseline (T1) and at the end of treatment after a period of 12 weeks (T2). Parent–infant dyads eligible for study participation were randomly assigned to fPIP or TAU with a 1:1 allocation, stratified for infant sex, age range (16−40 weeks or 41−60 weeks), and parent-reported primary regulatory symptoms (crying/sleeping or feeding). Randomization was electronically generated using randomizer.at.[20]

To conceal treatment allocation, a research assistant blinded to the study's hypotheses placed tickets in identical envelopes in containers ordered by stratum. Another person blinded to hypotheses was asked to sequentially pick an envelope for each participant. The result was communicated to the parent by the interviewer at the end of the first appointment. Cases in fPIP were allocated to a therapist according to their availability. If allocated to TAU, parents were instructed to consult their pediatrician. Pediatricians received a letter with the results of the clinical interview and were asked to treat the case according to their standard procedure for ERD during a time frame of 12 weeks.

For T1, the experimenters (A.G. and a research associate) were blinded to group. Study participants were blinded to the study's hypotheses. It was impossible to blind treatment providers to group allocation or experimental hypotheses. Emotional availability ratings based on the videos were completed by the 2 experimenters by the end of the study. To ensure blinding, they started coding only after

the end of the trial, and videos were re-coded to conceal for group allocation and time point. Data analysts were blinded partly to group.

Approval for the research was obtained from the Medical Faculty of Heidelberg University (No. S-541/2013 approved November 4, 2013).

Sample Characteristics

Data were collected from February 2014 to March 2018 in the department for Family Therapy at Heidelberg University Hospital. In total, 73 cooperating pediatricians in 62 practices referred families for study participation. Families were referred if they reported significant crying, sleeping, or feeding difficulties. In addition, some families self-referred in response to public advertisement, websites, and flyers/posters distributed in gynecological, pediatric, and osteopathic practices, parent–infant groups, and crèches (nurseries).

Inclusion criteria required the infant to be between 4 and 15 months of age, to have been born at full term (>37 weeks of gestation), and to fulfill diagnostic criteria for sleeping disorders, feeding disorders, or regulation disorders of sensory processing according to DC:0-3 R[21] or for persistent excessive crying, sleeping, or feeding disorder, according to the guidelines recommended by the German Society of Child and Adolescent Psychiatry, Psychosomatics and Psychotherapy[22] (AWMF guidelines). The minimum age criterion of 4 months instead of 6 months was changed after 5 months of recruiting, as we had to unexpectedly decline a high percentage of younger patients for study participation. The rationale for the initial age criterion was to exclude infants presenting with excessive crying related to infant colic, which typically remits spontaneously by 3 months,[23] and thus would have led to inflated treatment effects. The criterion of 4 months was deemed to be sufficient to rule out spontaneous remissions.[24] Pregnancy needed to be singleton, and primary caregivers needed to speak German. Families were excluded if infants had a medical diagnosis that would explain the regulatory problems, a tentative diagnosis of fetal alcohol syndrome, or a diagnosed disability or developmental disorder. A very high symptom severity of the primary caregiver (Symptom-Check-List-90R-S, Global Severity Index of $T>70$)[25] was another exclusion criterion, given that current mental illness of the parent was considered a contraindication for brief intervention.

Eligible parents were informed about treatment conditions and study design and were invited for study participation if they consented in a telephone screening. Self-report measures including sociodemographic questions were sent a week before T1. T1 was conducted with the primary caregiver and infant and consisted of the video-recorded parent–infant interaction, clinical interview, and the Symptom-Checklist-90R-S. Written informed consent was collected at the beginning of the session. Clinical diagnosis was assessed by 2 psychologists, each with several years of experience in PIP. Posttreatment data (T2) were collected 12 weeks after T1 by a research assistant. Self-report measures were sent to the family a week before T2. T2 consisted of the video and a satisfaction questionnaire.

Treatments

Focused PIP. fPIP took place at the department for Family Therapy at Heidelberg University Hospital. It consisted of 1 double session (90 minutes) and 3 single sessions (50 minutes) with the primary caregiver or both parents and the infant, delivered within a 12-week period by postgraduate students in psychoanalytic training. By the end of the study, therapists had on average 7.6 years of training (SD = 1.19, range = 6−10 years). Experience working with families ranged from 3 to 9 years (mean = 4.78, SD = 1.92). Therapists were assigned a range of 4 to 21 families, with an average of mean of 8.89 (SD = 5.49).

All therapists received the manual and a 2- to 3-hour training in fPIP. Treatment fidelity was ensured through bi-weekly supervision with M.C., checklist-based self-monitoring, and video-based assessment of adherence. Adherence was assessed on a random sample of 33 treatments with the psychodynamic scale of the Comparative Psychotherapy Process Scales[26] extended for fPIP-specific therapeutic techniques.[16] The fPIP adherence scale consists of 21 items rated on a 7-point Likert scale from 0 (not at all characteristic) to 6 (extremely characteristic). Interrater reliability of the total score between 2 raters (S.K. and a research assistant) was high (intraclass correlation coefficient [ICC] = 0.93). A treatment was regarded as adherent if 90% of the interventions were implemented at least once during the 4 sessions, which is equivalent to a rating of ≥2. The criterion was fulfilled for 28 treatments (84.85%).

Treatment as Usual. The German guidelines for pediatric routine examinations recommend using developmentally oriented education and counseling in the case of regulatory problems.[27] The standard procedure followed by cooperating pediatricians for treating ERD in this study was assessed by the middle of the recruiting period with a response rate of 53.2%. The questionnaire consisted of interventions scored regarding their frequency on a scale from 0 (never) to 4 (very often). The standard duration of a consultation was assessed as 5, 10, 15, or >15 minutes. Almost 75% of the practitioners reported seeing patients for >15 minutes. Figure 1 presents the frequencies of interventions.

The pediatricians' qualifications status was assessed by reviewing official and private websites. Almost 65% stated having at least 1 additional qualification. The most frequent qualification was in psychosomatic medicine (61.29%), followed by early prevention (8.06%), psychiatry (4.84%), and psychotherapy (3.23%).

The number of consultations with the pediatrician on topics unrelated to ERD in the fPIP group, and the additional support sought of parents in both groups, were assessed at T2.

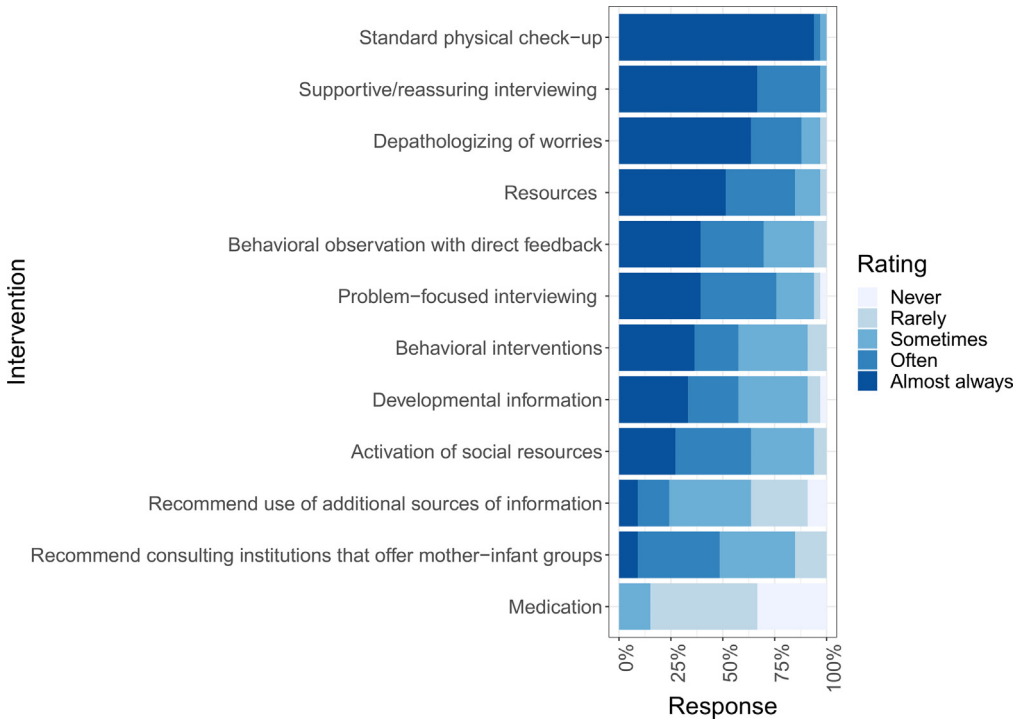
Measures

Clinical Interview. The structured clinical interview was developed for the purpose of this study. It assesses symptoms of sleep onset disorder, night waking disorder, feeding disorders, and regulation disorders of sensory processing (axis I; DC:0−3R), as these symptoms on a descriptive level reflect the definition of ERD.[2] However, persistent excessive crying syndrome is not mentioned as a distinct clinical category, and diagnostic criteria of DC:0−3R are poorly described. Therefore, we additionally used the diagnostic algorithms defined by the AWMF-guidelines on persistent excessive crying, sleep onset disorder, night waking disorder, and feeding disorder, which are operationalized by exact time frames for symptom behavior.[22] The Parent–Infant Relationship Global Assessment Scale (PIR-GAS; DC:0−3R) was used to assess parent–infant relationship dimensionally from 0 to 10 (documented maltreatment) to 91 to 100 (well adapted).[21]

Infant Regulatory Symptoms. The Questionnaire for Crying, Feeding and Sleeping (QCFS) dimensionally assesses regulatory symptoms.[28] A total of 49 items measure the scales (1) crying, fussing, and sleeping, (2) feeding, (3) dysfunctional parental co-regulation, and a global sum score. Frequency questions are rated on a 4-point Likert scale from "never/rarely" to "always/every day." The global score was used because it reflects problems in all behavioral areas. Cronbach's α was good (0.81).

The 96-Hour Behavior Diary. The diary of crying, sleeping, and feeding behavior[29] is similar to widely used parental diaries of infants' behavior. Parents record the frequency and duration of each behavior in 15-minute intervals on 4 consecutive days. Frequency and duration scores of the respective behaviors are summed for 96 hours. Additional questions refer to, for example, the effectiveness of co-regulation. The diagnostic algorithms of the AWMF guidelines for sleep onset, night waking, persistent excessive crying, and feeding disorders were used to create cutoffs for the respective behavioral variables. Remission was defined as fulfilling clinical cutoff criteria at T1 but not at T2. We tested the validity of the clinical cutoffs using classifications

FIGURE 1 Frequency of Interventions Used by Cooperating Pediatricians for Treating Early Regulatory Disorders



Note: *Please note color figures are available online.*

from the clinical interview as ground truth. The results pointed to distinct validities for the diagnoses. Readers wishing further information may contact the first author.

Parenting Stress. The German Parenting Stress Index (PSI) was used to assess self-reported parenting stress with 48 items.[30] Items are rated on a 5-point Likert scale from "strongly disagree" to "strongly agree." The 2 main scales, the child domain and the parent domain, are summed for a global score. Cronbach's α of the global score was excellent (0.93).

Psychological Distress and Depression. The German Symptom-Checklist (Symptom-Checklist-90R-S, SCL)[25] was used to assess self-reported psychological distress and depression. The 90 items are rated on a 5-point Likert scale from "not at all" to "extremely." A *T*-score >70 on the Global Severity Index (GSI) reflects high to very high psychological distress. Cronbach's α was excellent for SCL-GSI (0.95) and good for the subscale depression (SCL-DE; 0.86).

Maternal Self-Efficacy. The German translation of the Maternal Self-Efficacy Scale (MSES) was used to assess perceived behavioral competence in parenting.[31] The MSES had been translated into German language via back-and-forth translations. Discussion of the final version was supervised by a native English speaker. The scale consists of 10 items rated on a 4-point Likert scale from "not good at all" to "very good." Cronbach's α of the scale was acceptable (0.76).

Parental Reflective Functioning. The German version of the Parental Reflective Functioning Questionnaire (PRFQ)[32] assesses 3 scales with 18 items: (1) interest and curiosity in mental states (IC), (2) certainty of mental states (CMS), and (3) prementalizing (PM), which signifies deficits in parental reflective functioning (PRF). Items are rated on a 7-point Likert scale ranging from "strongly disagree" to "strongly agree." Cronbach's α was low for PRF-PM and IC (0.59; 0.50), and acceptable for PRF-CMS (0.73).

Emotional Availability. The Emotional Availability Scales (EAS; 4th edition)[33] were used to assess the quality of dyadic interaction during 15 minutes of free play. Following the protocol, the experimenter instructed mothers to interact with their child as they usually would at home, and left, as the interaction was video recorded. Four dimensions of parental emotional availability (EA; sensitivity, structuring, non-intrusiveness, and nonhostility) and 2 child dimensions (responsivity and involvement) were assessed on six 7-point scales. The EA composite scores for parent (EA-Parent) and child (EA-Child) were derived by summing the corresponding scores. Two raters were trained by Z. Biringen and certified for reliability. ICCs were calculated for 68 of the 273 rated videos (24.9%) and ranged from 0.79 to 0.89.

Patient Satisfaction Questionnaire. The German Version of the Patient Satisfaction Questionnaire (ZUF-8)[34] assesses patients' satisfaction with treatment. The questionnaire was adapted for fPIP. It consists of 8 items scored on a 4-point Likert scale, which are summed up to a total score. Higher scores represent more satisfaction. Cronbach's α of the total score was good (0.81).

The measures used to test study hypotheses have been shown to have adequate reliability and validity. There are no psychometric studies for the German version of PRFQ and MSES or the clinical interview and derived cutoffs to assess remission with the 96-hour diary.

Statistical Analysis

Power analysis was run for repeated-measures analysis of variance group (fPIP, TAU) by time (T1, T2) using g-power.[35] Because of the heterogeneity in the field of parenting interventions, with effect sizes ranging from large[12,13] to small,[9] we opted for a medium effect size of $\eta^2 = 0.04$. With an ICC of 0.2, a power of $\beta = 0.90$, and an α of 0.05, a sample size of 160 was needed.

Group differences in the metric variable of the primary and secondary outcomes were tested by the time-by-group interaction term in repeated-measures analyses of variance. χ^2 Tests were used to test for group differences in remission rates. For all analyses, intent-to-treat samples were used.

The data included 12.2% missing values. Visual inspection of pattern plots did not suggest systematic missing data. We imputed missing data using multiple imputation by chained equations[36] with 40 iterations. No multivariate outliers were found, as the largest Mahalanobis distance was smaller than the χ^2 critical value of 132.3. Homogeneity of variances was tested via the Levene test, and adjusted degrees of freedom were used wherever the assumption did not hold. R version 3.5.2 was used in all statistical analyses.[37]

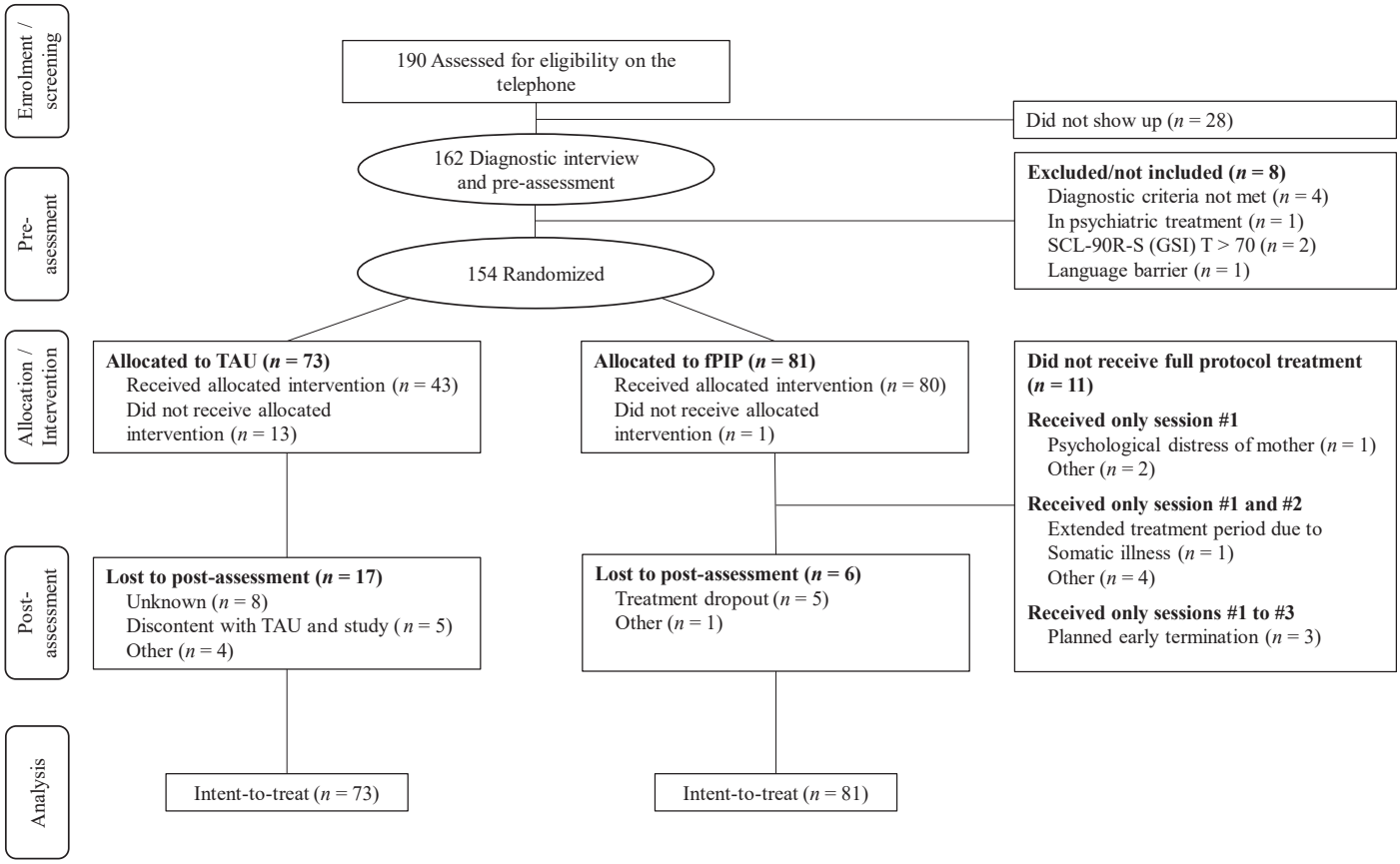
RESULTS

Study Participants

There were 190 parents who expressed their interest in study participation and underwent screening for eligibility via telephone. Among these, 28 canceled the first appointment or did not show up. Eight families were excluded from participating after pre-assessment, resulting in a final sample of 154 families randomized to TAU (n = 73) or fPIP (n = 81). Figure 2 displays the participant flow.

Table 1 describes sample characteristics at baseline. All of the primary caregivers were the infants' mothers. The quality of the parent–infant relationship (PIR-GAS) was

FIGURE 2 CONSORT Diagram



Note: *fPIP = focused parent–infant psychotherapy; TAU = treatment as usual.*

rated on average as perturbed, indicative of a disturbed relationship quality. Mothers on average reported increased psychological distress (T = 58) and parenting stress (percentile range of 90).

We started implementing the PRFQ only after 16 months of recruiting because of the former lack of self-report measures on PRF. Therefore, data on the PRFQ is restricted to a subsample of 98 (TAU, n = 50; fPIP, n = 48) that did not differ from the total sample with regard to demographic and clinical characteristics (p values >.06).

Treatment Completion and Satisfaction

fPIP. A total of 69 cases (85.19%) allocated to fPIP received 4 sessions, according to the manual, with a mean of 3.69 treatment sessions (SD = 0.83, minimum = 0 and maximum = 4, median/mode = 4). There were 5 treatment dropouts. In 54 fPIP cases (66.66%), the father participated in at least 1 session. Ten mothers reported having consulted their pediatrician during the treatment period. However, in all cases, the reason for consultation was a standard physical check-up.

TAU. A total of 42 control families (57.53%) consulted their pediatrician at least once with the purpose of receiving counseling for their child's problematic behavior. The number of sessions ranged from 1 (31.51%) to 5 (1.37%), with a mean of 1.69 sessions (SD = 0.95) and median/mode of 1.

Additional Support. Additional support was sought by 47 families (30.52%; TAU = 27; fPIP = 20). They reported having sought help from their midwife, alternative practitioners, early childhood intervention services, physiotherapists, or in parent–infant play groups. Families in the TAU group sought significantly more outside support [$\chi^2(1) = 4.87$, $p = .022$].

Treatment Satisfaction. Mothers in fPIP (mean = 27.25, SD = 3.40) reported being significantly more satisfied with the treatment [$t(124.39) = -9.30$, $p < .001$] compared to mothers in TAU (mean = 19.60, SD = 4.00).

Assessment Completion

Rates of assessment completion were 76.71% in TAU and 92.59% in fPIP. In TAU, significantly more participants

TABLE 1 Demographic and Clinical Characteristics at Baseline for Each Treatment Group

Characteristic	TAU (n = 73)	fPIP (n = 81)	Total (N = 154)	TAU vs fPIP Significance
Infant				
Female child, n (%)	29 (39.73)	38 (46.91)	67 (43.50)	$\chi^2(1) = 0.81$, $p = .369$
Age, mo, mean (SD)	8.28 (2.97)	8.84 (3.20)	8.57 (3.10)	w = 2650.5, $p = .268$
First-born child, n (%)	49 (67.12)	49 (60.49)	98 (63.64)	$\chi^2(1) = 0.723$, $p = .393$
Diagnosis				
Persistent excessive crying, n (%)	6 (8.22)	8 (9.88)	14 (9.09)	$\chi^2(1) = 0.13$, $p = .721$
Sleep onset disorder, n (%)	46 (63.01)	53 (65.43)	99 (64.29)	$\chi^2(1) = 0.10$, $p = .754$
Night waking disorder, n (%)	60 (82.19)	71 (87.65)	131 (85.06)	$\chi^2(1) = 0.90$, $p = .342$
Regulation disorder of sensory processing, n (%)	34 (46.58)	42 (51.85)	76 (49.35)	$\chi^2(1) = 0.43$, $p = .513$
Feeding disorder, n (%)	9 (12.33)	11 (13.58)	20 (12.99)	$\chi^2(1) = 0.05$, $p = .818$
Sum of regulatory disorders, median (min; max)	2 (1; 5)	2 (1; 5)	2 (1; 5)	w = 2646.5, $p = .237$
PIR-GAS, mean (SD)	7.37 (1.05)	7.37 (1.02)	7.37 (1.03)	$t(152) = -0.00$, $p = .998$
Mother				
Age, y, mean (SD)	33.43 (4.42)	33.10 (4.40)	33.26 (4.40)	$t(152) = 0.47$, $p = .637$
Mother has high school or higher education, n (%)	54 (73.97)	59 (72.84)	113 (73.37)	$\chi^2(1) = 0.21$, $p = .651$
Mother married, n (%)	56 (76.71)	64 (79.01)	120 (77.92)	$\chi^2(1) = 0.12$, $p = .731$
Mother of German origin, n (%)	60 (82.19)	73 (90.12)	133 (86.36)	$\chi^2(1) = 2.76$, $p = .097$
SCL (GSI), mean (SD)	0.50 (0.34)	0.60 (0.40)	0.55 (0.37)	$w = 2512.5$, $p = .108$

Note: Diagnosis according to DC: 0–3R[21] *or AWMF guidelines.*[22] *fPIP = focused parent–infant psychotherapy; max = maximum; min = minimum; PIR-GAS = Parent–Infant Relationship Global Assessment Scale; SCL (GSI) = General Severity Index of the Symptom-Check-List-90R-S; TAU = treatment as usual.*

were lost to T2 [$\chi^2(1) = 7.62$, $p = .006$]. Participants who dropped out were significantly more often of non-German citizenship compared to assessment completers [$\chi^2(1) = 8.26$, $p = .004$] but did not differ significantly regarding other sample characteristics or outcome measures at baseline.

Primary and Secondary Treatment Outcomes

Table 2 presents primary and secondary outcomes at each time point by treatment group, and gives an overview of the analysis of variance results.

Primary Outcomes. A significant interaction effect was found for the QCSF ($F_{1,152} = 8.71$, $p = .004$, $\eta^2 = 0.05$, CI = 0.01–0.12) signifying a stronger effect of fPIP on the overall level of infants' regulatory symptoms compared to TAU. The frequency score of remitted patients from night waking disorders was significantly higher in fPIP [$\chi^2(1) = 4.71$, $p = .030$, odds ratio {OR} = 3.12, CI = 1.21–9.22] (Table 3). No group differences were found for remitted patients from sleep onset, persistent excessive crying, or feeding disorders.

Secondary Outcomes. A significant interaction effect was found for SCL-GSI ($F_{1,152} = 13.72$, $p = .000$, $\eta^2 = 0.08$, CI = 0.03–0.16), with mothers in fPIP reporting decreased psychological distress in comparison to mothers in TAU. Likewise, an interaction effect was found for SCL-DE ($F_{1,152} = 10.20$, $p = .002$, $\eta^2 = 0.06$, CI = 0.02–0.13), favoring fPIP compared to TAU in terms of less depression. There were trends suggesting a greater increase on MSES in fPIP ($F_{1,152} = 3.25$, $p = .073$, $\eta^2 = 0.02$, CI = 0.00–0.07) and a greater decrease on PRF-PM in fPIP ($F_{1,96} = 3.26$,

TABLE 2 Analysis of Variance for Time, Group, and Time-by-Group Effects on Primary and Secondary Outcomes Comparing Treatment as Usual with Focused Parent–Infant Psychotherapy

	Before			After			Time			Group			Time × Group		
	TAU Mean (SD)	fPIP Mean (SD)	Total Mean (SD)	TAU Mean (SD)	fPIP Mean (SD)	Total Mean (SD)	*F*	*p*	η^2 [CI]	*F*	*p*	η^2 [CI]	*F*	*p*	η^2 [CI]
QCFS	2.24 (0.19)	2.23 (0.21)	2.23 (0.20)	2.21 (0.28)	2.06 (0.27)	2.13 (0.28)	19.47	.000	0.11 [0.05—0.20]	6.23	.014	0.04 [0.00—0.10]	8.71	.004	0.05 [0.01—0.12]
SCL-GSI	0.50 (0.34)	0.60 (0.40)	0.55 (0.37)	0.60 (0.48)	0.44 (0.44)	0.52 (0.47)	0.64	.426	0.00 [0.00—0.04]	0.21	.647	0.00 [0.00—0.03]	13.72	.000	0.08 [0.03—0.16]
SCL-DE	9.60 (7.20)	12.46 (8.39)	11.10 (7.95)	10.37 (8.51)	8.33 (8.22)	9.30 (8.39)	4.80	.030	0.03 [0.00—0.09]	0.15	.701	0.00 [0.00—0.02]	10.20	.002	0.06 [0.02—0.13]
PSI	131.52 (31.60)	135.44 (28.86)	133.58 (30.15)	130.41 (34.32)	128.23 (32.08)	129.27 (33.07)	3.85	.051	0.03 [0.00—0.08]	0.04	.851	0.00 [0.00—0.02]	2.07	.152	0.01 [0.00—0.06]
MSES	31.77 (3.28)	31.80 (3.91)	31.79 (3.61)	31.86 (3.83)	33.04 (3.78)	32.48 (3.84)	4.44	.037	0.03 [0.00—0.08]	1.41	.238	0.01 [0.00—0.05]	3.25	.073	0.02 [0.00—0.07]
PRF-PM[a]	1.57 (0.68)	1.64 (0.70)	1.61 (0.69)	1.58 (0.60)	1.44 (0.52)	1.51 (0.56)	2.68	.105	0.03 [0.00—0.10]	0.07	.792	0.00 [0.00—0.03]	3.26	.074	0.03 [0.00—0.11]
PRF-IC[a]	5.19 (0.95)	5.12 (0.85)	5.16 (0.90)	4.93 (1.03)	4.92 (0.93)	4.93 (0.98)	5.86	.017	0.06 [0.01—0.15]	0.07	.799	0.00 [0.00—0.03]	0.12	.728	0.00 [0.00—0.04]
PRF-CMS[a]	3.84 (1.16)	4.07 (0.98)	3.95 (1.08)	3.96 (1.06)	4.47 (0.95)	4.21 (1.04)	6.32	.014	0.06 [0.01—0.15]	4.00	.048	0.04 [0.00—0.12]	1.78	.185	0.02 [0.00—0.08]
EA-Parent	22.46 (3.36)	23.60 (2.68)	23.06 (3.07)	22.24 (3.34)	23.09 (2.87)	22.69 (3.12)	1.85	.176	0.01 [0.00—0.06]	5.82	.017	0.04 [0.00—0.10]	0.31	.576	0.00 [0.00—0.03]
EA-Child	9.00 (1.87)	9.01 (1.96)	9.01 (1.91)	13.97 (2.11)	14.15 (2.43)	14.07 (2.28)	4616.90	.000	0.97 [0.96—0.97]	0.08	.782	0.00 [0.00—0.02]	1.35	.247	0.01 [0.00—0.05]

Note: All F tests calculated with df = 1, 152, except for the scales of the PRFQ df = 1, 96. EA-Child = Composite Child score of the Emotional Availability Scales; EA-Parent = Composite Parent score of the Emotional Availability Scales; fPIP = focused parent–infant psychotherapy (n = 81); MSES = Maternal Self-Efficacy Scale; PRF-CMS = Certainty of Mental States scale of the Parental Reflective Functioning Questionnaire; PRF-IC = Interest and Curiosity scale of the Parental Reflective Functioning Questionnaire; PRF-PM = Prementalizing scale of the Parental Reflective Functioning Questionnaire; PSI = Parenting Stress Index; QCFS = Questionnaire for Crying, Feeding and Sleeping; SCL-DE = Depression scale of the Symptom-Check-List-90R-S; SCL-GSI = General Severity Index of the Symptom-Check-List-90R-S; TAU = treatment as usual (n = 73).

[a]*Sample size with PRFQ scores was smaller (TAU, n= 50; fPIP, n = 48).*

TABLE 3 Remission Rates From Clinical Diagnoses of Sleep Onset, Night Waking, Persistent Excessive Crying, and Feeding Disorder in Treatment as Usual Versus Focused Parent–Infant Psychotherapy

	TAU (n = 73)		fPIP (n = 81)					
	Remitted n (%)	Not remitted n (%)	Remitted n (%)	Not remitted n (%)	χ^2	*p*	OR [CI]	RD
Sleep onset	16 (21.92)	57 (78.08)	20 (24.69)	61 (75.30)	0.05	.829	1.17 [0.55−2.51]	1.13
Night waking	6 (8.22)	67 (91.78)	18 (22.22)	63 (77.78)	4.71	.030	3.12 [1.21−9.22]	2.70
Persistent excessive crying	4 (5.48)	69 (94.52)	9 (11.11)	72 (88.89)	0.93	.335	2.10 [0.64−8.35]	2.03
Feeding	18 (24.66)	55 (73.34)	17 (20.99)	64 (79.01)	0.12	.726	0.81 [0.38−1.74]	0.85

Note: *fPIP = focused parent–infant psychotherapy; OR = odds ratio; RD = risk difference; TAU = treatment as usual.* df = *1.*

$p = .074$, $\eta^2 = 0.03$, CI = 0.00–0.11), but neither reached significance. None of the other variables yielded significant interaction effects.

DISCUSSION

This study tested the efficacy of fPIP, a brief psychodynamic-based therapy for treating ERD, by comparing it with TAU in a randomized controlled trial. In line with our hypotheses, fPIP was found to be superior to TAU in treating infants' regulatory symptoms (ie, the primary outcome). Mothers in fPIP reported in the QCSF a significantly greater decrease in excessive crying, disordered sleeping and feeding, and dysfunctional parental co-regulation strategies. According to the behavioral diaries, the remission rate of infants with night waking disorder (ie, the most prevalent diagnosis in this sample) was also significantly higher in fPIP than in TAU. Finally, fPIP was superior in decreasing maternal psychological distress and depression assessed with the SCL, which were our secondary outcomes. These effects, along with the low incidence of treatment drop-out, and mothers' reports of high satisfaction following treatment, all point to fPIP being a helpful and effective intervention. Overall, these results add to the existing evidence that psychodynamic PIP is effective in treating this population.[12-14]

Surprisingly, we did not find changes in rates of sleep onset, persistent excessive crying, or feeding disorders. Such results may be attributed to the low prevalence of clinically diagnosed persistent excessive crying or feedings disorders in our sample at baseline. Furthermore, the literature suggests that parenting interventions are often less effective in reducing crying behavior.[9] Also, similarly to previous studies,[11,38] we did not find fPIP to be significantly better than TAU in reducing parenting stress (PSI). It may be that treatments aiming to target primarily that aspect should be broader in scope, for example, addressing marital/partner satisfaction or parental health that is measured by the PSI.

Despite significant reductions of symptoms in infants and mothers, we did not find treatment effects on parental mentalizing, self-efficacy, and quality of parent–infant interaction. Our results showed only trends for superior effects of fPIP on increased maternal self-efficacy (MSAS) and decreased prementalizing (PRF-PM). Based on the literature,[11,14,39] it is possible that treatments of longer duration may be needed to transform the internalized representations in the parent[12] or the affective quality of the parent–infant interaction. Consistent with this, some studies have found such changes at a follow-up time point rather than at termination.[14,39]

This study has some limitations. First, participation required extensive assessments and may have attracted parents with a higher motivation for undertaking treatment. The higher drop-out among mothers without German citizenship could reflect a cultural characteristic related to treatment motivation and study participation. The generalizability of our findings should be further tested in studies investigating whether fPIP is effective in samples of more diverse, at-risk families.

The finding that mothers allocated to TAU often did not receive an intervention, were more often lost to follow-up, and reported lower satisfaction with TAU could have contributed to biases in our results. However, time effects in both groups and interaction effects on some outcome parameters both contradict the notion of a general bias toward worse effects in TAU. The fact that mothers in TAU sought additional help may have compensated for the lower application of pediatric TAU, and we did not control for dose effects of pediatric TAU or effects of additional outside support in both groups.

Based on the limited administration of TAU and the finding that most of the pediatricians, despite having general psychosomatic qualifications, did not have qualifications in psychotherapy or early prevention focus, TAU seems to be a weak comparison condition. Two-thirds of the pediatricians reported that their typical consultation lasted longer than 15 minutes. However, data concerning the exact length were not collected, which makes conclusions on the dose of TAU difficult.

The main effects of time suggested changes that may result from factors unrelated to either treatment. These could be age effects, spontaneous remission, or partial remission effects that did lead to change in overall regulatory symptoms and child dimensions of EA. To exclude those effects, a wait-list-control would have been necessary. However, given potential consequences to development in the absence of intervention, this was not considered to be ethical.

Other limitations are related to the measures included in this study. Interactive failures associated with ERD may more frequently appear during stress-related situations and not in free play interactions.[40,41] To generate more valid results, future studies of fPIP should assess the interaction quality in problematic situations. In addition, PRFQ and MSES are not validated in German, and the PRFQ scales showed low internal consistency.[42] Moreover, analyses on the PRFQ were underpowered; thus, the results obtained should be viewed with caution, and require future replication. Finally, the validity of the AWMF algorithms used as clinical cutoffs in 96-hour diaries yielded mixed results in our study and should be investigated in other samples.

Our results add to the evidence that brief psychodynamic-based PIP is effective in helping young families. Thus, its incorporation into psychotherapy training and health care systems would be beneficial. Future studies may compare fPIP with other therapy approaches to investigate active components and dose effects. Our data showed a high participation among fathers in the fPIP group. Based on the literature,[41,43] future studies should systematically investigate the effect of the fathers' involvement in fPIP on treatment outcome. In addition, future studies should include a follow-up assessment and should investigate differential responsiveness to treatment based on baseline mental health of parents and their infants in order to understand for whom fPIP is more effective.

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