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Exploring the feasibility and acceptance of a group- and family-based online intervention (GuG-Auf-Online) versus treatment-as-usual (TAU) for preventing mental health problems in the offspring of parents with depression: study protocol for a randomised controlled trial

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Abstract

Theoretical Background: Preventive interventions for children of depressed parents are a major public health priority. A Family- and Group-based Cognitive-Behavioral (FGCB) intervention has shown positive effects on child outcomes in randomised controlled trials (RCTs) in the USA and Germany.

Objective: This pilot study explores the feasibility and acceptance of a shortened (8-session) form of FGCB delivered via video-conferencing and supported by a mobile app ("GuG-Auf-Online"). GuG-Auf-Online will be evaluated as a cognitive-behavioural sub-form of multi-family therapy (MFT) evaluated within the multi-site "CHIMPS-NET" trial.

Methods: 60 families with i) at least one parent with a current or past episode of major depression, and ii) at least one child aged eight to 17 without a current psychiatric diagnosis will be recruited. Families will be randomly allocated to receive the GuG-Auf-Online intervention; n = 30) or no intervention (n = 30).

Results: We will first explore the acceptance and feasibility of GuG-Auf-Online by analysing uptake of the intervention, attendance and app-use. Ecological Momentary Assessment (EMA) will be used to track short-term changes in affect within the intervention group. The final aim is to explore whether the intervention is associated with changes in potential mediators: children's coping with stress, early maladaptive schemas (EMS) and/or parents' parenting skills.

Conclusion and Discussion: Children of parents with depression have an elevated risk of developing depression themselves yet face multiple barriers to accessing evidence-based prevention. This pilot study will explore the potential of a digitally-adapted evidence-based intervention to overcome these barriers. The study provides the necessary foundations for a future large-scale RCT.

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Trial registration: The trial was registered on 30th April 2021 with the German Clinical Trials Register (https://drks.de/search/en/trial/DRKS00023136).

Keywords: Children, Adolescent, Cognitive behavioural therapy, digital, EMA

Declarations

Ethical approvement and consent to participate

The study has been approved by the ethics committee of the LMU University Hospital Munich (Nr. 19-837). Informed consent to participate will be obtained from all participants including guardians of participating children. Children will provide assent to participate.

Consent for publication

The study findings will be disseminated via scientific publications, presentations at scientific and clinical conferences, as well as on the website of the research group (prodo-group.com) and via social media (see “Patient and Public Involvement”). Consent for publication will be obtained from all participants including guardians of participating children.

Availability of data and materials

The datasets generated during the current study will be made available from the corresponding author on reasonable request.

Competing interests

The authors declare they have no competing interests.

Funding

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Authors' contributions

Funding for the CHIMPS-NET trial was acquired by SWG and funding for the development of the app by BP. The GuG-Auf-Online intervention was developed by BP, JL, PG, CB, and GSK in collaboration with BC. All authors contributed to the conceptualisation of the study design. BP, SG and VD wrote the manuscript. All authors reviewed the manuscript.

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Background

Depression is the disease that causes most years lived in disability world-wide [1] and comes with high personal and economic costs. In Germany, depression is associated with an estimated €15.6 billion annually [2]. Several studies have shown that one of the biggest risk factors for depression is having a parent who has suffered from depression. The vast majority of adults who experience mental health problems such as depression are parents: 68% of women and 57% of men with mental health problems are parents [3]. Children with a depressed parent have around a 50% chance of developing depression themselves [4]. In children and adolescents, depression is associated with poorer social and educational outcomes [5, 6], and continues to exert its negative effect in their adult life by being linked to poorer work performance, more sick days, increased mortality via suicide, and lower marital and parent functioning [7]. In most countries, including Germany, children of depressed parents only receive formal mental health support once they fulfil the criteria of a psychiatric disorder themselves. Preventive interventions for children who themselves do not yet experience clinical levels of psychopathology are necessary for relieving the healthcare system in the long term.

Depression is likely to be passed from parent to child via a combination of biological (e.g. genetic), psychological (e.g. parent-child interactions) and social factors (e.g. financial difficulties) [8]. Thus, preventive interventions for children of parents with depression target modifiable mechanisms such as communication within the family [9], parent-child interactions [10, 11] and/or children's ability to deal with stress [12, 13]. A meta-analysis found that preventive interventions can be effective in reducing the risk of depression in children with depressed parents [14]. One such intervention is the Family- and Group-based Cognitive-Behavioral (FGCB) intervention [15]. One key component of the FGCB is to improve children's ability to cope with stress using the strategies i) acceptance, ii) distraction, iii)

engaging in positive activities and iv) positive/realistic thinking. Another key component of the intervention is teaching parents how to convey warmth and structure through their parenting despite their depression. The FGCB has shown positive effects in previous efficacy trials in the USA [15] and Germany (where it is called "Grow Up Healthy and Happy" or "GuG-Auf") [16]. However, a previous efficacy trial found that participating families had a relatively high socio-economic status [16] and reported the intervention to be too time-intensive. Together these findings question the accessibility of the intervention: families with a lower socio-economic status and with less time available might struggle to access the intervention. Other studies indicate that alongside the lack of motivation (a key symptom of depression) and financial pressures [17], parents with depression face increased daily hassles [18] and are often reluctant to seek professional help for their children [19]. The current study aims to address these barriers by evaluating a shortened version of GuG-Auf which is delivered via video-conferencing and supported with a smartphone application (app).

Digital tools have been explored as a means for making interventions to prevent and treat mental illness more accessible for some time [20]. Digital tools encompass a wide range of methods including smartphone apps, self-help websites and moderated chatrooms. In contrast with face-to-face interventions, where the participant has to travel to a particular location, digital interventions are associated with reduced time commitment and geographical independence. As such they may be suitable for families living rurally, those who have comorbid health conditions (who may not easily be able to travel), single parents (who may have increased childcare and work commitments), those who have antisocial working hours (who may not be able to attend during normal office hours) and/or those affected by parental depression (barriers described above). Indeed, a systematic review of 18 studies evaluating online services in facilitating mental health help-seeking in young people found that the online

setting may be helpful for people affected by the stigmatisation of mental illness who may put off attending clinical institutions (e.g. psychiatric clinics) to receive help [21].

Digital forms of evidence-based interventions such as cognitive-behavioural therapy (CBT) have been found to be effective in the *treatment* of adult [22] and youth [23] depression. It should nevertheless be noted that not all digital interventions are equal: therapist-supported ("guided") interventions are more effective than standalone ("unguided" or "self-guided") interventions [24]. Evidence-based digital interventions for the *prevention* of depression in children and adolescents are relatively sparse: a review of 146 preventive interventions which measured effects on the onset of depression and anxiety [25] identified just two digital interventions [26, 27]. Since then a further intervention ("CATCH-IT"), which is a 20-module online psychoeducation course for parents and their children, has been evaluated [28]. In a sample of 369 adolescents with sub-clinical symptoms of depression, positive effects on the time to depressive episode were found for those who received the intervention versus those who received general health education [28]. As far as the authors are aware, there are no digital interventions available for the children of depressed parents specifically.

The COVID-19 pandemic has brought about rapid advances in one specific guided digital tool: video-conferencing (VC). In the field of digital mental health, VC is used interchangeably with the terms "Webinar" [29] or "Videolink" [30] and common platforms include Skype, Zoom, Webex. VC involves using a PC, laptop, tablet of smartphone in order for patient and therapist to interact in real-time (via audio and video) without being physically in the same place. Whilst VC emerged during the COVID-19 pandemic as a second-choice alternative to face-to-face (F2F) psychotherapy, it has been evaluated as a means for making mental health interventions more accessible for some time [20]. Although some clinicians are concerned that VC has the potential to negatively impact the therapeutic relationship, studies comparing VC to F2F psychotherapy in the treatment of depression have found comparable

effectiveness in both forms of delivery [31, 32]. For example, in a (non-randomised) controlled study for adults with depression or anxiety who chose whether to receive group-based CBT via VC or group-based CBT F2F in a clinic, both groups were associated with similar reductions in symptoms [32]. A second study which randomly allocated adults with depression to receive CBT via VC versus F2F in an outpatient clinic, there were no differences between groups in terms of depressive symptoms or patient satisfaction [31]. One RCT even found VC to be superior to F2F treatment of children with depression [33]. In this study children received eight weekly sessions of CBT, either via VC or F2F [33]. Attendance was comparable in both groups, yet those who received CBT via VC showed a greater reduction in symptoms of depression [33]. The authors suggest this may either be a chance finding, or because children felt the VC delivery was more novel [33]. VC has also been used not only for individual psychotherapy but also to deliver group-based interventions [34]. For example, to support family caregivers of older adults with neurodegenerative disease [35] and to provide family interventions for mothers affected by post-natal depression [36]. In a systematic review of group-based VC in healthcare interventions VC was reported to be feasible "even for those with limited digital literacy" and highly acceptable due to participants being able to remain at home and having relatively few concerns about privacy [34]. As far as the authors are aware no studies have evaluated the use of video-conferencing in the *prevention* of depression.

The current study is part of the multi-site Children of Mentally Ill Parents Network (CHIMPS-NET) trial evaluating the implementation of various forms of family therapy to support children of mentally ill parents (ClinicalTrials.gov registration: NCT04369625). The main trial focuses on the effectiveness of family-therapy for parents with any form of mental illness and children aged four to 18 years. One arm of the trial focuses on multi-family therapy (CHIMPS-MFT) in particular, where eight sessions of family therapy are offered to a group of three to five families affected by any form of parental mental illness. Families are included if

192 children show first signs of mental illness but do not fulfil the criteria for a diagnosis. The
193 current sub-study takes place at a single site (Munich) and pilots a shortened and digitally-
194 delivered version of the FGCB intervention ("GuG-Auf-Online") for parents in Germany with
195 depression and their children aged eight to 17 years.

196 In GuG-Auf-Online the number of sessions in the intervention has been reduced from
197 12 (GuG-Auf) to eight. This is based on a previous evaluation of GuG-Auf in which families
198 reported the 12 sessions to be a hurdle to participating [37]. This has been achieved by reducing
199 the amount of time spent teaching each of the various parenting strategies and children's coping
200 strategies rather than removing strategies altogether. In GuG-Auf-Online, families are also
201 provided with psycho-educative material about the strategies in a specifically-developed
202 mobile app which they can access between sessions. Provision of basic psycho-educational
203 material in the app is also designed to allow more time during the sessions to discuss the
204 relevance of content to individual families. As such, we do not expect the reduction in the
205 number of sessions to be associated with significant reductions in effectiveness of the
206 intervention. Due to the ongoing COVID-19 pandemic, the intervention will be delivered
207 online via a video conferencing platform. We will assess the feasibility and acceptance of the
208 intervention by participating families, since as far as we are aware, just one study has
209 investigated service-users' experiences of psychological treatment or prevention via VC [38].
210 Ecological Momentary Assessment (EMA) will explore short-term changes in mood for
211 participants who receive the intervention. EMA is a data collection method that can capture
212 fluctuations of dynamic variables (e.g., symptoms of psychopathology, sleep, affect, etc.) by
213 measuring behaviour in real-time with high frequency and in the subject's natural environment
214 [33, 34]. EMA has the advantage that it diminishes recall biases thus enhancing accuracy,
215 increases ecological validity, and it reveals short term changes [33–36]. This is particularly
216 relevant for the current study since children are particularly prone to biases in retrospective

217 self-report [37]. Finally, we intend to involve families affected by parental depression in the
218 design, conduct and interpretation of the study (see Patient and Public Involvement; PPI for
219 details). Involving service users in research conduct is strongly recommended in order improve
220 the quality and relevance of research as well as increase the uptake of findings [39].

221 Objectives

222 The first aim is to assess the feasibility and acceptance of the GuG-Auf-Online
223 intervention. The second aim is to explore the effects of GuG-Auf-Online on short-term
224 positive and negative affect across the course of the intervention. Given the lack of previous
225 literature on high-frequency data in regard to such preventive interventions all analyses we be
226 exploratory rather than hypothesis-driven. The third aim of the study is to explore whether the
227 intervention has positive effects on the proposed mechanisms of action. We expect participants
228 who receive the GuG-Auf-Online intervention to show positive changes in i) children's coping
229 with stress, ii) children's tendency to adopt maladaptive schemas and iii) parents' parenting
230 skills. We will explore whether parental distress and children's experience of negative life
231 events predict which children benefit from the intervention. We make no predictions about the
232 precise time points at which the mediators and moderators have their effects.

233 **Methods**

234 This study protocol is reported in line with the international "SPIRIT" guidelines for reporting
235 a clinical trial protocol [40]. Important protocol modifications (e.g. early termination of the
236 trial, change in inclusion criteria, change in interventions) will be communicated to the ethics
237 committee and reported via the clinical trials registry and in any scientific publications resulting
238 from the study.

239 **Study Design**

240 As previously described, this pilot study is part of a the "CHIMPS-NET" trial
241 (ClinicalTrials.gov registration: NCT04369625; Study Protocol in preparation): a multi-site

project evaluating the implementation of psychotherapeutic interventions for parents with any form of mental illness and their children aged four to 18 years. One arm of the trial compares eight sessions of multi-family therapy (MFT) with treatment as usual (TAU) in families (recruited at 20 psychiatric clinics throughout Germany) affected by any form of parental mental illness. Within this arm of the trial, this pilot study tests the acceptance and feasibility of a group- and family-based intervention specifically targeted at parents with depression and their children aged eight to 17 years with mild to moderate symptoms of mental illness. This pilot study includes only those families recruited to the MFT arm at the Department of Child and Adolescent Psychiatry, Psychosomatic and Psychotherapy of the LMU University Hospital in Munich. All families in the CHIMPS-NET trial and this pilot study, irrespective of their group, take part in a total of four assessment sessions: baseline assessment (T1) prior to randomization, six months after baseline (T2), 12 months after baseline (T3), and 18 months after baseline (T4).

Participants, interventions, and outcomes

Eligibility criteria

Eligibility and exclusion criteria for participation in this pilot study are listed in Table 1.

Table 1 Eligibility and exclusion criteria

Families are eligible for study participation if:	
1	one participating parent has a primary diagnosis of major depressive disorder (current or past) according to DSM-5,
2	the participating child is aged eight to 17 and does not have a current psychiatric disorder (according to DSM-IV),
3	the parent with depression is insured with one of the public health insurance companies involved in the trial,

4	all participating family members have adequate German-language skills (determined by their participating in the diagnostic interview),
5	parents provide written informed consent for themselves and their child(ren) to take part in the study and to the data management policy (including video-recording of intervention sessions for the purposes of quality control and data processing by their health insurance company),
6	the participating child provides written assent to take part.
Families are excluded from study participation if:	
1	They have very poor interpersonal functioning deemed to be contra-productive for group-based intervention (score < 21 on the Global Assessment of Relational Functioning Scale; GARF;[41]),
2	a participating family member suffers from acute symptoms which may hamper their ability to take part such as suicidal tendencies, severe depression, acute alcohol or drug misuse, manic symptoms, severe personality disorder, acute psychotic symptoms or dissociative symptoms,
3	the participating child is undergoing treatment, including medication, for any mental illness,
4	they take part in family therapy during the course of the study period.

Note that use of DSM-5 criteria for parents and DSM-IV criteria for children is because the measures to assess mental disorder (M.I.N.I. and K-SADS-PL respectively) were selected by the main CHIMPS-NET trial and the current German version of the K-SADS-PL follows DSM-IV (not DSM-5) criteria. All siblings who meet the inclusion criteria can take part in the study and will be allocated to the same group. If both parents fulfil the study inclusion criteria, they may both take part. If the partner (or other adult living in the house with parenting

266 responsibilities) of the participating parent does not have a diagnosis of depression, they may
267 still take part in the study, providing they do not meet the exclusion criteria.

268 Intervention

269 "GuG-Auf-Online" (*Grow Up Healthy and Happy – Online*). GuG-Auf-Online is based on the
270 German version (GuG-Auf) [42] of the original Family Group Cognitive-Behavioural (FGCB)
271 preventive intervention developed and evaluated by Compas and colleagues [15]. The aim of
272 the 12-session manualized GuG-Auf intervention is to reduce the risk of depression for children
273 aged eight to 17 with a parent who suffers from depression. GuG-Auf contains three basic
274 components: psycho-education about dealing with depression in the family (sessions with the
275 whole family), individual sessions with children teaching them strategies for dealing with stress
276 (A-APP; acceptance, distraction, positive thinking and positive activities[1]) as well as individual
277 sessions for parents teaching them how to display warmth and structure throughout and
278 between depressive episodes. Children and parents have homework tasks to complete between
279 sessions and parents are encouraged to spend at least 15 minutes of quality time a day with
280 their child. Booster sessions are designed to increase the longevity of effects by trouble-
281 shooting any problems families encounter in implementing the learnt skills into everyday life.
282 Each group contains three to five families.
283 GuG-Auf-Online (manual available upon request) has been shortened from 12 sessions to eight,
284 including two (rather than four) booster sessions. This is based on a previous evaluation of
285 GuG-Auf in which families reported the 12 sessions to be a hurdle to participating [37]. Whilst
286 the time taken to teach each strategy is reduced in GuG-Auf-Online, the number of strategies
287 taught remains the same as in GuG-Auf. Table 2 provides a comprehensive summary of the
288 contents of each session. Paper-based workbooks, which contain psycho-educative material
289 and diaries for completing homework, have been replaced in the modified version by an online

[1] in German: Akzeptanz, Ablenkung, positives Denken, positive Aktivitäten

application (browser- and smartphone-based) designed to be more accessible for participants on-the-go. In GuG-Auf-Online participants will be asked to read through psycho-educative content *prior* to each session (in GuG-Auf this was supplied *during* the session) with the goal of providing more time in the session for personalising content for individual families. In order to accommodate the needs of vulnerable families during the Covid-19 pandemic a video conferencing tool with end-to-end encryption (Cisco Webex E2E) will be used to deliver the sessions online rather than face-to-face. The use of Cisco Webex E2E for this study was approved by the data protection officer of LMU University Hospital. A number of adaptations to GuG-Auf were made to accommodate the online delivery of GuG-Auf-Online. These include the use of power-point slides rather than paper workbooks for parents and children and omitting name badges due to the availability of a naming function in Webex. In GuG-Auf, the parents were separated from children by moving to a different room within the clinic. In GuG-Auf-Online breakout rooms will be created for this purpose and children will be encouraged to move to a different room where possible. To maximise participant attendance participants will take part in a technical test session prior to the first GuG-Auf-Online session. This session is designed to trouble-shoot any technical and logistical problems which participants may encounter (e.g. wifi connection, size of screen, functionality of camera and microphone etc.). To maximise the use of the app for training between sessions, we will send participants daily push notifications (see "Ecological Momentary Assessment (EMA) of mood states (aim 2)" for more details).

Table 2 Overview of the GuG-Auf-Online intervention

Session	Topic(s)
	Sessions with children and parents together

1	Introduction of group leaders and families; Psychoeducation about depression and familial transmission; Causes and symptoms of stress	
2	Reactions to stress	
3	Introduction to "A-APP" coping strategies	
	Individual sessions for children and parents	
	Children	**Parents**
4	"A-APP" stress coping strategies: Acceptance and Distraction	Helpful parenting strategies I: praise, attentive listening, consciously ignoring, seeking help
5	"A-APP" stress coping strategies: Positive Thinking and Positive Activity	Helpful parenting strategies II: structure, reward, consequences
6	A-APP role plays	Parenting strategies role plays Parenting during an episode of depression Supporting children using "A-APP"
	Booster sessions with children and parents together	
7	Solving problems that arise Strengthening stress coping and parenting skills Planning for potentially challenging situations	
8	Solving problems that arise Strengthening stress coping and parenting skills Farewell	

Group leaders will be trained in using the manual by the first author. They will have at least either an undergraduate degree in Psychology (or similar) or be a trainee psychotherapist. To enhance treatment fidelity, group leaders will be offered regular supervision by BP and all sessions will be video-recorded. A random sample (25%) of videos will be selected by an

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independent assessor and assessed in terms of their accordance with an adherence checklist. Group leaders will complete attendance and homework sheets to monitor how many sessions each family attends.

Control condition

Children assigned to the control condition receive no formal intervention, which in the local health care system equates to treatment as usual (TAU). The no intervention control condition will enable us to test a true preventive effect of the intervention (see elsewhere [13] for a discussion of how active-control conditions restrict conclusions about preventive effects), in addition to being able to estimate the clinical value in comparison to currently available support. All families from the EG and TAU are still entitled to receive support from the usual care system including advice centres regarding parenting issues, treatment for parental illness and professional assessment of children's mental health. All of these factors will be documented by the research team and where necessary included in the analyses. In the case that children receive professional treatment for a mental illness, their data will be excluded from the current study. Families allocated to TAU will have access to the app which provides psycho-educative content after the study period.

Outcomes

Table 3 provides an overview of the assessment and outcome measures collected in this study.

Table 3 Measures to assess eligibility and intervention outcomes

Function	Construct	Instrument	T1	T2	T3	T4
Eligibility criteria	Diagnostic status (parent)	M.I.N.I	X			
	Diagnostic status (child)	K-SADS	X			
	Psychopathology of partner[2]	SCL-90-R	X			
	Family functioning	GARF	X			

[2] The partner is defined as either the other parent of the child or the life-partner of the depressed parent who has regular contact with the child and is involved in their parenting.

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Implementation outcomes (EG only)	Feasibility	Uptake of the intervention (who takes part), technical hurdles, attendance and app compliance	During and between intervention sessions			
	Acceptance	Self-developed evaluation forms	Weekly during the intervention			
		Self-developed semi-structured interviews	Upon completion of intervention			
	Affect & affect stability	PANAS	Daily over the course of the intervention			
Potential mediators	Parent-reported coping with stress (child)	RSQ	X	X	X	X
	Early Maladaptive Schemas (EMS; child)	DISC	X	X	X	X
	Parenting style	ESI	X	X	X	X
Potential moderators	Parental distress	BSI	X			
	Stressful life events (child)	CASE-C/P				X
Efficacy primary outcomes	Child self-reported internalizing symptoms	YSR (children aged ≥ 10 years)	X	X	X	X
	Parent-reported internalizing symptoms	CBCL (children aged 8-9 years)	X	X	X	X
Efficacy secondary outcomes	Diagnostic status (child)	K-SADS	X	X	X	X
	Child self-reported externalizing symptoms	YSR	X	X	X	X
	Parent-reported internalizing and externalizing symptoms	CBCL	X	X	X	X
	Child general well-being	KIDSCREEN-27	X	X	X	X
Harm measures	Negative effects of psychotherapy [3]	NEQ		X	X	X
	Change in child symptoms	K-SADS, YSR		X	X	X

Abbreviations: M.I.N.I: Mini International Neuropsychiatric Interview [43]; K-SADS-PL: Kiddie Schedule for Affective Disorders and Schizophrenia (present and lifetime version) [44]; YSR: Youth Self Report [45];

[3] EG only

KIDSCREEN-27 [46, 47]; SCL-90-R: Symptom Checklist 90 Items Revised [48]; CBCL: Child Behavior Checklist [45]; RSQ: Responses to Stress Questionnaire [49]; DISC: Dusseldorf Illustrated Schema Questionnaire for Children (DISC) [50]; ESI: Erziehungsstil-Inventar; BSI: Brief Symptom Inventory [51]; NEQ: Negative Effects Questionnaire [52]; GARF: Global Assessment of Relational Functioning [41], CASE-C/P: Child and Adolescent Survey of Experiences [53] PANAS: Positive and Negative Affect Schedule [45].

Eligibility criteria

Diagnostic status of the depressed parent will be assessed by an external rater using the Mini International Neuropsychiatric Interview (M.I.N.I.) [43]. The M.I.N.I. is a structured clinical interview covering the 17 most common psychiatric disorders of the DSM-5 and ICD-10. It is a common diagnostic instrument in clinical research and only takes 15 to 20 minutes while having good psychometric properties [43]. Inter-rater reliability is excellent, test-retest reliability is very good and correlations with other diagnostic instruments are good to excellent [54]. Staff members involved in diagnostic assessment will have a bachelor's degree in psychology or comparable and adequate training in the administration of the respective diagnostic measure.

The mental health of the non-affected parent will be assessed by the Symptom-Checklist-90-R (SCL-90-R) [48]. The SCL-90-R is a self-report questionnaire measuring somatic and psychological impairment. It comprises 90 items covering nine symptom scales: somatization, obsessiveness, depressiveness, social insecurities, anxiousness, aggressiveness, phobic fear, paranoid thinking and psychoticism. Internal consistency of the scales ranges from $\alpha = .64$ to $\alpha = .89$.

Family functioning as prerequisite for participation in the study will be assessed by the Global Assessment of Relational Functioning (GARF) [41]. The GARF consists of a 100-points-continuum scale that is based on three dimensions of relational functioning (problem solving, organisation, emotional atmosphere). The researcher will give a score based on their interaction

364 with the family at baseline assessment. The GARF has shown good to excellent inter-rater
365 reliability and small but significant correlations with other measures of interpersonal-
366 functioning [55].

367 Feasibility and acceptance (aim 1)

368 We will assess the feasibility of the intervention by recording attendance at the sessions and
369 recording any technical issues or hurdles which arise during the intervention. Furthermore, we
370 will assess how feasible the intervention is for families with varied backgrounds by observing
371 how the socio-economic status and demographic characteristics of participating families
372 (assessed at T1) compares to families in Germany in general. For this analysis we will use data
373 from the German national consensus
374 (https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/01/PD22_031_122.html). We
375 will assess acceptance of the intervention by asking participating families to complete weekly
376 evaluation forms and by conducting brief semi-structured interviews with families after they
377 have taken part in the intervention.

378 Ecological Momentary Assessment (EMA) of mood states (aim 2)

379 EMA will be used in the intervention (but not TAU) group to collect high-frequented (daily)
380 real-time data about the parents' and children's mood and stressful events in their daily life in
381 the week after each session (see Figure 1 for an overview). Reminders will be sent every day
382 at 5 p.m. with another reminder every hour if the participant has not responded to the questions
383 yet. Participants have time until midnight to complete the questionnaires.

384 **Figure 1: EMA data collection during the weekly intervention sessions**

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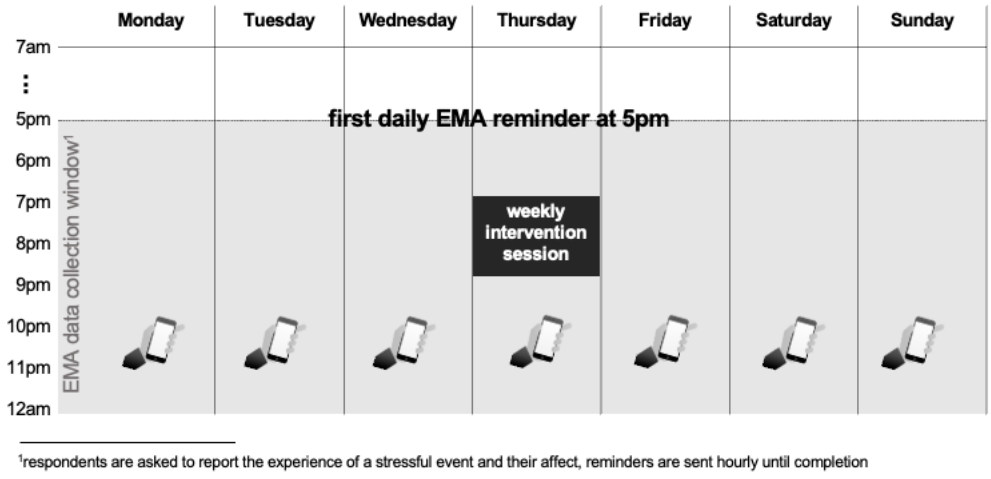

Our first measurement, collected daily, is the German version [56] of the Positive and Negative Affect Schedule (PANAS)[57] to assess negative and positive affect. The PANAS is a 20-item instrument with ten items assessing negative affect and ten items assessing positive affect. Every item consists of one adjective describing either negative or positive affect. Participants are asked to rate the extent to which they momentarily feel like this adjective on 5-point Likert scale (1 = “not at all”, 2 = “a little”, 3 = “moderately”, 4 = “quite a bit”, 5 = “extremely”). The German version of the PANAS is a well-established and commonly used affect measure with high reliability (α = .86)[56]. Moreover, it is one of few measures that has good reliability in an EMA context specifically [58]. Our second measure, also collected daily, is whether parents and children have experienced a stressful event that day.

In both children and parents we will explore i) the course of affect change across the week proceeding each session (e.g. sudden gains versus gradual improvements), ii) whether some sessions are associated with greater changes in affect than others, iii) whether the intervention is associated with changes in the stability of affect over time, iv) whether affect stability is associated with coping strategies etc., and v) how affect within the same family is associated (i.e. do changes in parental affect correlate with child affect). EMA data may help to identify how our intervention works and why it might not work for some individuals.

Empirical findings show that EMA is feasible for both children above the age of seven [59] and adults suffering from acute depression [60]. Hence, we do not expect any compliance issues stemming from young age or burden of disease. However, since our EMA period will be longer than in many previous studies, we will take some additional measures recommended to ensure compliance [59]. First, the healthy partner and both therapists will be instructed to support the children and the depressed parent in complying to the EMA. Second, we will feedback the data to the participants which was shown to be an effective incentive [59]. Third, we will use a measurement burst design (see Heron et al., 2017[59]) for the period around the two booster sessions. This means that there is a three-week EMA break between session six and seven, and another one between session seven and eight.

Potential mediators (aim 3)

The efficacy of the intervention at changing symptoms of psychopathology (YSR, CBCL), onset of disorder (K-SADS) and wellbeing (KIDSCREEN-27) across the four measurement time points (0-, 6-, 12-, 18-months after baseline) will be assessed elsewhere as part of the main CHIMPS-NET trial. The study reported in this manuscript will examine between-group differences in the potential mechanisms behind the intervention: child coping with stress, EMS and parenting style. The extent to which these effects are moderated by parental distress and stressful life events will be explored.

Children's coping with stress will be assessed by the parent-report of the Responses to Stress Questionnaire adapted for children of parents with depression (RSQ) [49]. It consists of 57 items about coping and involuntary stress responses. Responses to most items must be given on a 4-point-Likert scale (1 = "not at all"; 4 = "a lot"). A few items provide checklists instead.

Early Maladaptive Schemas (EMS) of the children will be measured by a self-report of the child using the Dusseldorf Illustrated Schema Questionnaire for Children (DISC;[50]). The DISC is based on Young's 18-schema-model and identifies adaptive versus maladaptive

schemas in childhood [50]. It consists of 36 items. All items belonging to the same schema are accompanied by a cartoon illustrating the respective schema. The DISC has a high test-retest reliability and convergent validity [50].

Parenting style will be assessed by the Parenting Style Inventory ("Erziehungsstil-Inventar"; ESI;[61]) which will be filled in by the child. The ESI consists of 60 items with twelve items per subscale. The subscales are support, restrictiveness, praise, punishment, and inconsistency. The ESI is designed for children who are eight years or older. The internal consistency of the subscales ranges from $\alpha = .77$ to $\alpha = .92$. Retest coefficients between $r_{tt} = .51$ and $r_{tt} = .72$ were reported [61].

Parental distress of the depressed parent will be assessed by a self-report using the Brief Symptom Inventory (BSI; [51]). It is a shortened version of the SCL-90-R [48] and consists of 53 items. It measures the impairment caused by somatic and psychological symptoms on nine scales (for scales see SCL-90-R above). The internal consistency of the scales ranges from $\alpha = .39$ to $\alpha = .75$. Retest-reliability (after one week) varies from $r = .73$ to $r = .92$.

Stressful life events will be measured using the German-version of the Child and Adolescent Survey of Experiences (CASE-C/P; [53]). The questionnaire is filled out by both the parent and child and consists of 38 pleasant or unpleasant events that the child may have experienced in the past 12 months. The CASE demonstrates good test-retest reliability ($r = .75$) and good correlation with an interview-based measure of stressful life events [53].

Possible harms arising from the intervention will be monitored by using the Negative Effects Questionnaire (NEQ; [52]). The self-report measure contains 32 possible negative effects for which participants rate their negative impact on five-point Likert scale (0 = "not at all", 4 = "extremely"). It differentiates between negative effects attributed to the treatment and those that are possibly caused by other circumstances.

Patient and public involvement (PPI)

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Patients and the public will be involved in the study as information recipients and as information providers. We will use the study group website (prodo-group.com), social media channels (e.g., Facebook, Instagram), as well as email distribution to disseminate knowledge attained from the study. Social media allow us to engage with patients and the public bidirectionally. We will include feedback from the families who took part in the evaluation of GuG-Auf [37] in the development of GuG-Auf-Online and collect feedback from parents with depression when we interpret the findings of this study. To encourage active feedback, we will set up focus groups and an advisory board which will provide us with the children's and parents' perspective on the study and help us improve our research.

Procedure

Participant timeline

Figure 2 gives an overview over the participant timeline. When both the child and their parent are interested in taking part and make contact with the study team, they will be informed about the details of the study (and the inclusion/exclusion criteria) over the telephone. If they are suitable and still interested, a separate appointment for a screening session will be made. Here the parent and child will be given an overview of the study (including the fact that their allocation to the EG/TAU group will be decided at random) and written informed consent will be taken from both the parent and child by VD or another member of the research team.

Figure 2 Participant flow

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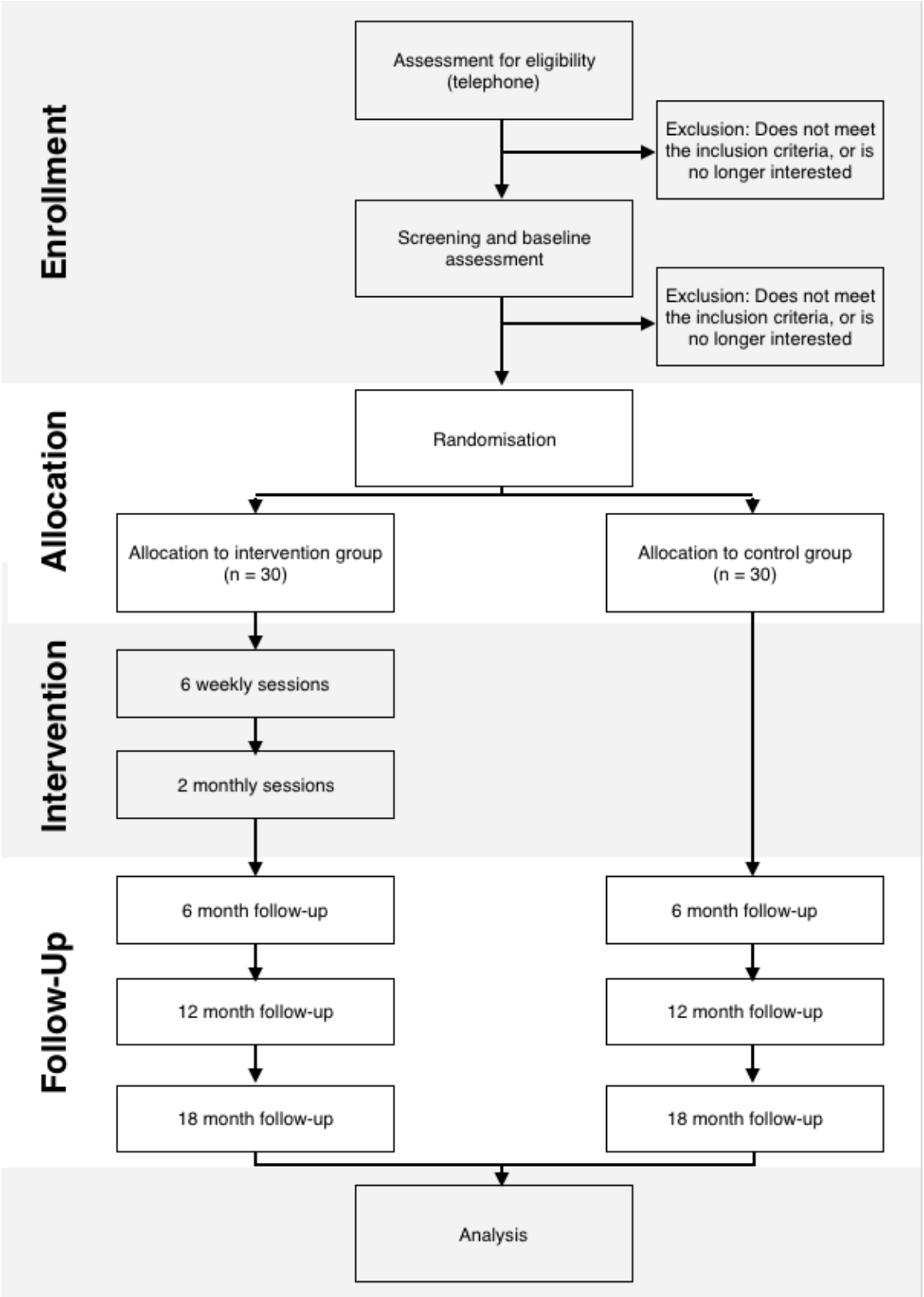

Following a diagnostic (screening) interview, baseline measures of all outcome measures (see below) will be administered. If only one parent attends the screening session, the other parent will nevertheless be asked to complete a self-report questionnaire about symptoms of general psychopathology (SCL-90-R). The SCL-90-R is a standardized instrument with clinical cut-offs. After the appointment, a decision about the family's suitability for participation in the study will be made, and if suitable, randomisation will be performed (see "Allocation").

Sample size

The sample size for this pilot study was influenced by sample size calculations for the multi-site CHIMPS-NET trial, in which 60 families per trial site were determined necessary to detect effects of the intervention on primary outcomes. This was deemed to be sufficient to test the feasibility and acceptance of GuG-Auf-Online because it would allow us to run around six groups in total. Importantly, based on our previous experience [42] this number is deemed to be feasible and realistic within the timescale of the study (three years). Assuming a similar effect size to the one achieved in our previous evaluation of the GuG-Auf intervention (d = .46; [42]) power of .80 and alpha error rate of .05 a total sample of 32 would enable us to detect an interaction between group (EG, TAU) and time (T1-T4) on the potential mechanisms. In a previous study [42] 19% of the 100 families randomized dropped out during the study period. Randomising 60 families in total would allow for 47% drop-out.

Recruitment

Families will be recruited in Bavaria through a large network of institutions and care givers obtained in a previous trial of a similar intervention [42]. Based on a previous study we expect roughly 30% of families to be recruited through public adverts, 30% through adult psychiatric clinics, 20% through a city council database of families with children in the age range of the study and the remaining 20% through community centres and word of mouth. Each family will receive €50 upon completion of the four assessment sessions.

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Assignment of interventions

Allocation

At each site, eligible families will be randomized (allocation ratio 1:1) to one of two conditions: intervention (EG) versus TAU. Randomisation for the CHIMPS-NET trial will be performed by a biometrician at the Institute for Medical Biometrics (UKE) who will generate a list of random numbers using a computer-program. None of the researchers or clinicians at the Munich site will have access to the list. VD and BP will enrol participants and inform the biometrician when a family fulfils the inclusion criteria for the study. The biometrician will inform them about which group the family should be assigned to. VD and BP will inform participants about which group they have been assigned to. As soon as 3-5 families have been randomized to receive the EG, a new intervention group will begin.

Blinding

Due to the nature of the intervention, participating families will be informed about their group allocation (EG, TAU). Outcome assessors will also be aware of the family's group allocation.

Data collection, management, and analysis

Data collection methods and data management

Members of the research team in Munich will maintain a list of participant names and contact details in on a secure server at the Department of Child and Adolescent Psychiatry, Psychosomatics and Psychotherapy of the LMU University Hospital. Since this list will also contain the participant's unique ID number, only members of the study team will have access to it. Paper-pencil questionnaires labelled with participant's unique ID number will be sent to families via the postal system with a stamped addressed envelope for them to be returned. Families will be reminded to complete questionnaires via telephone and email contact with the research team. The research team in Munich will check questionnaires for completeness upon receiving them and where necessary ask families to complete missing items/sections. Returned

questionnaires will be kept in a secure location at the research centre in Munich. Since the data form a part of a larger trial lead in Hamburg, a digital (scanned) copy saved as a password-protected file will be emailed to the main trial centre in Hamburg where data will be managed via the CTC North. Digital data such as audio recordings of the diagnostic interviews and video recordings of the intervention will be kept on a secure server at the Department of Child and Adolescent Psychiatry, Psychosomatics and Psychotherapy in Munich and sent to the CTC North as password-protected files via email for quality control purposes. All data will be kept locally and at the CTC North for 10 years upon which it will be deleted. Researchers within the project will be given limited access to the data for the purposes of analyses. The intervention sessions will be delivered via a video conferencing tool which conforms to EU data protection regulations and is approved for use in psychotherapy. Families will use the mobile app "SNS" to complete homework tasks between intervention sessions and daily EMA items. The app is owned by ccSYS which conforms to EU data protection regulations. All data collected via the app and stored on the ccSYS server will be fully anonymized.

Statistical methods

The first aim of the study is to assess the feasibility and acceptance of the intervention by participating parents and children and involves descriptive rather than statistical analysis. The second aim of the study is to explore changes in positive and negative affect via EMA within the EG. These data will be analysed in an exploratory way.

To explore whether families who receive GuG-Auf-Online show expected improvements in children's coping with stress, children's EMS and parenting style (aim 3) quantitative statistical analysis will be conducted using SPSS for Windows and R and JASP for Mac OX. T-tests on between-group (EG, TAU) differences in the various outcome and confounding variables at baseline will be conducted to check whether randomization was successful. An intention to treat (ITT) approach will be taken in which data from all randomized

participants will be included. Since there is the possibility that some participating children start psychotherapy during the course of the study, additional analyses may be conducted in which these children are excluded, to exclude the possibility that participation in psychotherapy contributes to the study outcomes. To test the hypothesis that positive effects of the GuG-Auf-Online intervention are associated with improvements in children's coping with stress, children's cognitive schemas and parents' parenting style we will conduct multi-level models (MLM) including all four measurement points. Each of the outcome measures will be predicted by the treatment condition (dummy-coded with TAU as 0 and with EG as 1), time variables (i.e., DT1, DT2, and DT3 coded as 1 for T2, T3, and T4 respectively), and the condition-time interactions. The model is represented as:

Y = Condition + DT1 + DT2 + DT3 + Condition*DT1 + Condition*DT2 + Condition*DT3

All the outcome measures will be log-transformed prior to the model estimation. We will assume random effects for the intercept and time dummies to allow the parameters to vary across individuals, unless there are any convergence problems.

To test the predictors of the GuG-Auf-Online intervention, regression models will be run in which intervention (GuG-Auf-Online, TAU) is included as an independent variable and children's coping, EMS and parenting style as the dependent variables. Potential predictors (parental distress, children's experience of negative life events) will be included and their interaction with the independent variable tested.

Harms

Existing studies of preventive interventions for families with a parent who is, or has, suffered from depression, provide no evidence of any associated risks or complications [14]. Despite this low risk, spontaneously occurring side-effects of the intervention will be documented by the study leaders and will be discussed in regular supervision sessions. Since psychiatric symptoms are monitored over the course of the study (T1-T4), any worsening of a child's

symptoms will be detected. In such a case or upon the family's request, treatment options will be discussed with the affected families, including the opportunity to receive treatment in the clinic for child and adolescent psychiatry. Any child of either group can start therapy at any point of the study if it becomes necessary. Participants may continue to participate in the intervention if they do not have acute psychiatric problems which limit their ability to participate (see exclusion criteria). Participating families as a whole or any single participant can withdraw from the study at any time without giving reason and without consequences.

Partners who receive a diagnosis of depression for the first time during the study period will be encouraged to seek treatment at the clinic for psychiatry. Continued participation in the study is nevertheless possible.

To detect other negative side effects and harms that may arise from our intervention, parents and children will be asked to complete the Negative Effects Questionnaire (NEQ) [52]. Other adverse effects that may occur in relation to psychological interventions include deterioration of existing symptoms and emergence of new symptoms [62, 63]. These will be monitored by standardized clinical interviews administered at T1 to T4 with participating children (data analysis reported elsewhere).

Trial status

Recruitment started in Autumn 2020 and will be completed in December 2022. The delivery of the intervention is expected to be completed in May 2023. Data collection will be completed by December 2023. Data analysis has not yet begun.

Discussion

Children of parents with depression have an elevated risk of developing depression themselves yet families affected by parental depression face multiple barriers to accessing evidence-based prevention. These barriers include increased daily hassles [19], lack of motivation to travel, reluctance to attend professional services [20] and financial pressures [21]. The current pilot

study aims to address these barriers by evaluating a shortened version of GuG-Auf which is delivered via VC and supported with a smartphone app (GuG-Auf-Online). Previous research has shown that online interventions may improve access to support for people affected by the stigmatisation of mental illness who may put off attending clinical institutions to receive help [21]. Furthermore, VC has been found to be equally effective [31], if not superior [33], to F2F mental health intervention. By providing the therapist-led intervention via video-conferencing (and supported by a mobile app) the aim of GuG-Auf-Online is to bring prevention to the homes of families affected by depression. As far as the authors are aware, this is the first study investigating a digital family- and group-based preventive intervention for families with parental depression.

A possible limitation of the study may be the representativeness of the sample since parents who are relatively high functioning, have an awareness of their children's mental wellbeing, and/or insight into their depression may be more likely to participate in the trial. Families may also have enhanced digital literacy. These features may already contribute to an enhanced resiliency of the children. On the other hand, the online format of the intervention may be more appealing to families with financial pressure who live more remotely. To investigate the hurdles to participation in the intervention, a survey running in parallel to the current study is planned.

A second potential limitation of the study is the EMA approach to collecting data from families in the intervention group. Whilst EMA has the advantage of measuring behaviour in real-time (thus avoiding retrospective recall biases) and in the subject's natural environment (versus in the laboratory), it relies on participants regularly using the app. To minimise recall biases, participants will be required to complete EMA measures on a daily basis between the intervention sessions. To maximise compliance, participants will be sent regular reminders to

use the app, will be reminded and encouraged by the group leaders, and will be able to access their own data (something which is known to improve compliance [64]).

Conclusion: This pilot study provides the necessary foundations for a future large-scale RCT study of the effectiveness and implementation of GuG-Auf-Online. It also makes a broader scientific contribution to the emerging field of telemedicine. Furthermore, it may help lay the foundation for closing a gap in the German health care system.

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629 **List of abbreviations**

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A-APP	acceptance, distraction, positive thinking and positive activities
BSI	Brief Symptom Inventory
CASE-C/P	Child and Adolescent Survey of Experiences (Child and parent report)
CBCL	Children Behaviour Checklist
CBT	Cognitive-behavioural therapy
CHIMPS-NET	Children of mentally ill parents Network
COVID-19	Coronavirus disease 19
CTC	Clinical Trial Center
DISC	Duesseldorf Illustrated Schema Questionnaire for Children
DJI	Deutsches Jugendinstitut
DSM-5	Diagnostic and Statistical Manual of Mental Disorders 5
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders IV
EG	Experimental group
EMA	Ecological Momentary Assessment
EMS	Early Maladaptive Schemas
ESI	Erziehungsstil-Inventar
EU	European Union
FGCB	Family- and group-based cognitive-behvioural intervention
GARF	Global Assessment of Relational Functioning
G-BA	Gemeinsamer Bundesausschuss
GuG-Auf	Gesund und Glücklich Aufwachsen
ITT	Intention to treat
K-SADS	The Kiddie Schedule for Affective Disorders and Schizophrenia
LMU	Ludwig-Maximilians-Universität
M.I.N.I	Mini Neuropsyachtric Interview
MLM	Multi-Level-Modelling
NEQ	Negative Effects Questionnaire
OR	Odd's ratio
PANAS	Positive and negative affect schedule
PPI	Patient and Public Involvement
RCT	Randomised controlled trial
RSQ	Responses to Stress Questionnaire
SCL-90-R	Symptom Checklist 90-R
SEM	structural equation modelling
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
TAU	Treatment as usual
UKE	Universitätsklinikum Hamburg-Eppendorf
USA	United States of America

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VC	Video-conferencing
YSR	Youth Self Report

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