Parental relationship and child development: A study protocol for a randomized controlled trial for strengthening couples and children from pregnancy until four years after birth

Guy Bodenmann  
University of Zurich

Céline Stadelmann  
Universität Zurich  
https://orcid.org/0000-0002-8476-378X

Peter Zimmermann  
Bergische Universität Wuppertal

Alexandra Iwanski  
Bergische Universität Wuppertal

Mirjam Senn  
University of Zurich

Anne Milek  
University of Münster

Valentina Rauch-Anderegg  
Massachusetts General Hospital / Harvard Medical School

Fabienne Meier  
University of Zurich

Study protocol

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Abstract

Background The transition to parenthood is a critical phase for couples and often relationship relational well-being (i.e., relationship satisfaction) deteriorates. As parents’ relationship well-being is a significant predictor of children's well-being, this decrease is also critical for children. Thus, strengthening couples during the transition to parenthood seems particularly important. Different intervention programmes targeting the transition to parenthood reported positive effects on relationship satisfaction, communication and child adjustment. This study protocol describes a randomized controlled trial for two couple-focused interventions, targeting the enhancement of partners’ relational skills (communication, dyadic coping, problem-solving, self-regulation in relationships) with the aim to improve relational well-being, partners’ well-being, coparenting and, consequently, foster healthy child development.

Methods/design We randomly assigned mixed-sex couples to a high or low dose intervention or a waiting list control condition. The high dose intervention consists of a training of relational skills, whereas in the low dose condition participants receive a psychoeducational movie. Outcomes are assessed over 11 time points from the third trimester of pregnancy until four years after birth assessing self-report and home observations of couple- and parent-child interactions. Primary outcomes include relational skills, individual and relational well-being and coparenting; a secondary outcome is healthy child development. Statistical analyses include multilevel modelling, structural equation modelling as well as standard statistics.

Discussion The aim of this study is to support families with couple-focused interventions and thus improve relational skills, relationship well-being, coparenting, individual well-being, and healthy child development. If the intervention reveals to be effective, we will target a broader dissemination.

Background And Rationale

A large body of research documents a considerable decline of relational well-being (i.e., relationship satisfaction) during the transition to parenthood (TTP) [1–4]. This deterioration is often associated with an increased level of relationship distress. Half of the couples becoming parents reach a clinically level of relationship distress within the first 18 months after birth [5] and another 30% show a small to moderate decline in relationship satisfaction [1, 6], which often persists for many years [7]. This repeatedly reported decline in well-being after TTP is often associated with impaired individual well-being. After birth of the first child, 25–50% of mothers experience short-term depressed mood and 10–15% suffer from postpartum depression [8]. Parents with psychopathology during pregnancy show prolonged depression and report a peak rather than a decrease of stress twelve months postpartum [8]. Thus, TTP is likely accompanied by a decline of both individual and relational well-being.

Importance of parental individual and relational well-being for child development
Independent from severity, depressive symptoms of mothers and fathers after birth have a strong impact on child development [9, 10]. Similarly, poor parental relational well-being is a significant and powerful predictor of decreased child well-being [11, 12] and increases the likelihood for the development of child psychopathology [13]. Predictors of poor relational-well-being are predictors of poor child well-being as well. For example, parental destructive and unresolved conflicts in particular affect child well-being negatively on a behavioural, emotional, physiological, and social level [14, 15]. It has been shown that destructive parental conflicts interfere with sensitive, involved parenting, and consequently threaten attachment security [14, 16]. On the other hand, higher relationship well-being is significantly associated with supportive coparenting [17], which in turn is related to better child adjustment [18]. Thus, the importance of relationship education during TTP is particularly evident, not only in an attempt to strengthen parents’ relationship but also in an effort to create promising developmental conditions for the child.

Relevance of relational skills for relational well-being

Stress during the TTP affects the individual and relational well-being of both partners. Relational skills such as communication or the way the partners cope with stressful circumstances communally as a couple (i.e. dyadic coping) may buffer detrimental effects of TTP [19]. A meta-analysis, not specific to the TTP, documents the importance of dyadic coping for relationship satisfaction [20] and it has also been shown to be predictive for partner’s parenting stress during the TTP [21]. Similarly, couples’ communication is a powerful predictor of relationship satisfaction and mediates the effects of stress on the relationship [22]. During TTP couples are more prone for deteriorations of couples’ communication [23, 24] as well as lower dyadic coping [25] and therefore, an intervention focusing on relational skills might be particularly important in this stage of life.

Effects of intervention programs during TTP

Meta-analyses document small but mostly positive effects of couple-focused interventions during TTP [26, 27]. Shapiro and Gottman [28] reported positive findings of a couple-focused intervention during pregnancy regarding relationship satisfaction, postpartum depression and hostile couple communication at three and 12 months after birth of the first child. Schulz et al. [3] found a less steep decline in relationship satisfaction in couples becoming parents who had participated in a couple-focused intervention, compared to a control group six months postpartum. Couple CARE for Parents, another evidence-based prevention programme, reduced negative couple communication significantly at six months postpartum [29]. This programme yielded significant effects even in the 2.5 year follow up, particularly in high-risk couples [29]. Daley-McCoy, Rogers, and Slade [30] found that a low-intensity prenatal intervention was able to weaken the deterioration of relationship satisfaction in women, whereas in men, results reported improved couple communication and lower psychological distress. Additionally a positive impact of relationship intervention on coparenting has been reported [31]. Positive treatment
effects on child adjustment and family violence were further reported [32]. In sum, there is convincing empirical evidence for the benefit of strengthening couples during TTP.

**Objectives**

We aim to strengthen couples during the TTP by increasing their awareness of the impact of TTP on their relationship and teaching them potentially crucial relational skills with cognitive-behavioural training (within the high dose intervention) or with a psycho-educational movie (within the low dose intervention). Both interventions should help couples to maintain or improve individual and relational well-being as well as coparenting, and subsequently favourable child development (see Figure 1). The study examines short- and long-term effects of two couple-focused interventions (low and high dose) in comparison to treatment as usual during TTP.

*Figure 1. Mediation model of couple-focused interventions on child outcomes*

**Study design**

This randomized controlled trial is a multimodal prospective longitudinal study including both parents and their first child. We collect self-reports and behavioural data at 11 times, from the 27th week of pregnancy to age four of the child (see Figure 2). The multimodal measurements include questionnaires on couples’ variables as well as on child outcomes. Furthermore, interactions of couple conflict (internal stress) and dyadic coping conversations (external stress) are videotaped several times before and after birth until the age of four of the child. At children's age three, mother-child and father-child interactions are observed in an experimental setting.

**Methods And Analysis**

**Study aim and setting**

This study aimed to prevent relationship deterioration and thereby enable healthy child development by teaching relationship skills to couples across TTP. Data are collected in the German-speaking part of Switzerland. Licenced psychologists at the University of Zurich and the University of Applied Sciences in Olten offer one-day workshops for the relational skills training to the high dose intervention group. Afterwards, midwives continue the skills training by conducting coached couple conversations at couples’ homes. The low dose group receives a one-hour psychoeducational video at the same time point as the workshops take place for the high dose intervention group. Videos of all couples’ interactions are coded by trained coders at the University of Zurich and videos of parent-child interactions at the University in Wuppertal.
Participants

We included couples who were: (1) being in a mixed-sex committed relationship of at least one-year duration, (2) becoming parents for the first time, and (3) speaking and understanding German. Exclusion criteria to ensure comparability of groups are: (1) having children from previous relationships, (2) twins, (3) mental disorders of the mother, and (4) currently in treatment for psychological, physical or relational problems. We exclude couples retrospectively if birth complications arise.

To determine the necessary sample size for our research questions we rely on the power calculation of the Monte-Carlo Studies [33]. A sample size of 210 young parents (70 per group) will provide high power (> 0.90) to detect a moderate effect size difference between the three treatment conditions at \( p = .05 \) [34]. Additionally, participants are followed closely to minimize drop-out rates which in turn will increase statistical validity and power of the planned analyses. In sum, data of \( N = 210 \) couples will be feasible and satisfy statistical requirements.

Participants are recruited at different hospitals in the German-speaking part of Switzerland or via social media platforms. Participants will be given 300 Swiss Francs (= 306 US dollars) for complete participation at all time points (see Figure 2 for participants’ timeline).

Figure 2. Participant timeline

Randomization and Blinding

Couples are randomly assigned to the three treatment conditions (low dose, high dose, waiting list control) after completing measures at T1 by the study coordinator using block randomization of 10 couples per group. In case of logistical and administrative problems (trainings are only deliverable at two sites) couples are randomly assigned to the low-dose or control condition. Participants are informed about group membership via e-mail after randomization. Except from study coordinators, all involved researchers, data collectors and behavioural coders are blinded about group membership. They are not unblinded under any circumstances.

Interventions

High dose intervention (skills training)

The high dose intervention group participates in the Couple Care and Coping for Parents programme (CCC-P), which is a blend of two evidence-based relationship education programmes: the Couples Coping Enhancement Training (CCET) [35] and Couple CARE for Parents [36]. CCC-P is a one-day workshop, delivered by a licensed psychologist at the 30th week of pregnancy. The workshop consists of psycho-educational and self-reflection elements and a strong focus on the behavioural training of relational skills.
(communication, dyadic coping, problem-solving, self-regulation in relationships). With respect to specific needs during TTP, additional topics are addressed (i.e., role changes, task distribution, sleep and sexuality after birth). The core components of the workshop are dyadic exercises, where couples are prompted by trained psychologists (ratio: two couples per one trainer) in improving their communication, dyadic coping and problem solving [37]. Three types of conversations are trained (couple conflict (internal stress), positive experience with the partner (wishes) and an external stress experience, meaning an individual stressor of each partner). To promote constructive communication, both partners are alternately in the role of speaker and listener and are encouraged to apply speaker and listener rules. For strengthening stress-related self-disclosure, listening and appropriate dyadic coping, couples are trained in the *three-phase-method* [37]. Within problem solving, couples learn the *six-step-problem solving technique* [38]. To ensure full privacy, each couple performs the training exercises in separate rooms. Couples are coached in every second conversation. During the five home visits, a midwife continues the skills training at couples’ homes (2 hours). Additionally, partners receive self-reflection and self-regulation tasks about a certain topic (e.g., infant care, parental self-efficacy, affection and sexuality, division of labour, expectations regarding the future).

**Low dose intervention (psycho-education)**

Participants in the low dose group are asked to watch an interactive movie, including psycho-education on changes related to TTP. Short theoretical inputs are rounded off by narrated experiences of six couples that recently became parents and talk about changes related to the birth of their child with regards to sleep and energy, household division, mutual support, and sexuality. The movie aims at increasing couples’ awareness of challenges emerging during TTP and contains tips on relational skills, but no coaching exercises. At the end of the movie, ideas about how to implement gained knowledge into daily life are provided. Each couple receives an individual access code via e-mail to stream the movie or a hard copy if preferred. To check if couples watch the movie, the online access to the movie is tracked and couples are asked questions about it.

**Waiting list control**

The waiting list control condition consists of the treatment as usually offered by hospitals after the birth of the child (TAU) and contains no comparable intervention elements of the couple-focused intervention as offered to the low and high dose group. After completion of the first nine time points, couples in this group can either watch the movie or participate in the workshop.

We investigate treatment as usual as a control group to establish the natural development of relationships to which we can compare the development with the intervention.

**Adherence to CCC-P (high dose intervention)**
All workshop providers receive an intensive training and need to be licensed to deliver CCC-P. Psychologists are recruited from trained and licenced CCET providers. Midwives receive a specific CCC-P training and need to successfully pass a final exam. CCC-P-sessions are delivered upon a standardized manual and checklists. Protocol adherence is evaluated by audiotapes of home visits and specific checklists regarding the content that has to be delivered. Further, midwives receive supervision and individual feedback based on the audiotapes.

**Study outcomes**

Primary study outcomes are directly targeted by the intervention, such as relational skills, individual and relational well-being and coparenting. We hypothesize that secondary outcomes, which are child-related outcomes, will be indirectly affected by the intervention through various skills (see Figure 1). This is a multimodal study using self- and partner-report as well as behavioural observation for primary and secondary outcomes. All variables are assessed with standardized scales, observational situations, and coding systems with approved psychometrics. Instruments developed by the authors will be evaluated for reliability and validity. In case of a lacking German translation, the standard procedure is applied (translation—back-translation—evaluation and adaptation). Figure 3 presents the outcome measures and the time of application.

*Figure 3. Schedule of enrolment, interventions, and assessments.*

**Primary outcomes (variables targeted by the intervention)**

*Relational skills* are assessed by self- and partner report of *communication* with the Marital Communication Questionnaire (MCQ) [39] measuring positive and negative marital communication behaviours in romantic relationships according to the SPAFF coding system [40] and of *dyadic coping* with the Dyadic Coping Inventory (DCI) [41] measuring communication of stress, supportive dyadic coping, common dyadic coping and negative dyadic coping. *Self-regulation in relationships* is assessed with the Self-regulation for Effective Relationships Scale (SRER) [42] measuring the degree to which partners are working toward a successful relationship. Observations of relational skills are conducted by trained examiners who visit couples at home and ask them to have three eight-minute conversations. To assess *couples’ stress and coping behaviour* they are asked to talk about each partners’ recent most stressful external stress experience. Therefore, each partner evaluates the burden of different areas of external stress. The sequence of whose topic will be discussed first is randomized across couples. Conversations are held in private. To assess *couples’ conflict communication* for the third conversation both partners rate the impact of different areas of internal stress and choose one for the conflict discussion. Couples are invited to behave as they usually do. As known from international research, these conversations show high ecological validity.
**Individual skills** are assessed with the German translation [43] of the BriefCOPE questionnaire [44] measuring effective and ineffective individual coping strategies and the Negative Emotion Regulation Inventory (NERI) [45] measuring individual parental emotion regulation and the intensity of emotional experiences in situations commonly inducing fear, anger, and sadness [46].

**Individual well-being** is measured with psychopathological symptomatology assessed with the Depression, Anxiety and Stress Scale (DASS-G) [47], parental Stress is assessed with the Parental Stress Scale (PSS) [48] measuring positive and negative aspects of parenting and emotional vulnerability with the short version of the Emotional Vulnerability Questionnaire (EVQ) [49] measuring the intensity and frequency of feeling hurt.

**Relational well-being** is assessed with the Couples Satisfaction Index (CSI) [50] and the German version [51] of the Relationship Assessment Scale (RAS) [52], measuring relationship satisfaction and with the German version [53] of the Marital Satisfaction Inventory (MSI) [54] and the Sexual Activity Scale [55], measuring sexual satisfaction.

**Coparenting skills** are assessed with the Coparenting Scale for Parents with Preschool Children (CSPPC) [56], measuring parental cooperation, differences and conflict, triangulation and undermining.

**Secondary outcomes (indirect or long-term outcomes).**

Child outcomes are measured with both parent-report of sleep problems with the Brief Screening Questionnaire for Infant Sleep Problems (BISC) [57], parent report of eating and screaming behaviours of the child with a scale developed by the authors measuring breastfeeding or bottle-feeding behaviour, eating and screaming behaviour of the child and subjective disturbance. Emotional and behavioural problems in early childhood are assessed with the German version [46] of the Early Childhood Screening Assessment (ECSA) [58], measuring child internalizing and externalizing symptoms. Behavioural problems with peers are measured with a subscale of the German version of the Strengths and Difficulties Questionnaire (SDQ) [59]. Emotional competency of the child is assessed with a subscale of the KOMPIK [60]. Parent-child interactions are assessed by two examiners who videotape the family at home during seven experimental situations. Parent-child emotion regulation is assessed with situation eliciting fear (stranger approach, remote control spider) and anger (toy removal, losing game) in the child [61–63]. Child autonomy and parental autonomy support are assessed with one triadic (clean-up task) and two dyadic interactions tasks (semi-structured play task) with each parent separately [46, 64]. Child Attachment Security to each parent is assessed using the Attachment-Q-Sort (AQS) [65] based on videotapes of the complete home visit, including separations, reunions and additional information from the parents. Children’s emotional reactions during the tasks, will be coded based on a standardized coding system, which was reliably used in previous studies [46, 64].

Background information is collected with a broad variety of control variables that might influence outcome measures. Couples will provide information about their age, gender, nationality, marital status,
relationship duration, type of residence, current pregnancy, education, profession, and employment status (including hours per week spent at work) as well as their attitude towards pregnancy, parental support, time for leisure, family, child and work, household task division, attachment, positive parenting, stress, and mood state.

**Coding.**

Several trained coders independently code maternal, paternal, and child’s behaviours videotaped with the parent-child and couple interaction tasks. Couple interactions and parent-child interactions are coded by different teams. Training continues until inter-rater reliability (ICC>.80, Kappa >.60) is reached.

In the dyadic interactions, *dyadic coping* is coded with the System for Analysing Dyadic Coping (SDAD) [66], which allows micro-analytic coding of stress communication and dyadic coping. *Conflict communication* behaviour (positive and negative behaviours and affects) is coded with the *SPAFF* [40]. Each category is coded independently for women and men by one coder per subject.

In the parent-child interactions, *emotional reactions of the child* at facial, vocal, and behavioural level are rated based on a coding system developed and tested in a previous study [46]. Latency, intensity, duration, and quality of emotion are observed in the course of all triadic situations. *Child Autonomy* is coded based on standardized coding systems developed and tested in a previous study [46]. *Parental Autonomy Support* and sensitivity in a play context are coded by use of the Sensitive and Challenging Interacting Play scale (SCIP) [67]. *Maternal and paternal responsiveness, scaffolding, cooperation, as well as overall sensitive challenging interactive play* are coded during the course of the ten-minute play interaction. *Attachment Security* is coded for each parent separately by use of the Q-Sort procedure resulting in continuous scores for security and dependency. Meta-analytical evidence shows the validity of the resulting security score [68].

**Data management**

Participants’ names are linked to research identifiers in one file, which is only available to the main researchers and password protected. All data is safely stored at the universities using research identifiers only, stored in locked cabinets and password locked hard disks in rooms only accessible to the research team. Each team member signs the Confidentiality Declaration of the University of Zurich (see Appendix). Data collectors will not have access to data and data coders to names or addresses of participants.

Based on previous experiences, the missing rate and dropout can be minimized by systematically engaging with the sample (e.g., Christmas cards, birth day cards, newsletters about study progress). Depending on the missingness mechanism [69] for drop-outs and/or missing measurement occasions, we will adopt different missing data management strategies.
**Statistical methods**

Besides standard statistics, approaches that account for nested data structure are required, including Multilevel Modelling, Structural Equation Modelling, and the combination of both. These analytic strategies allow for simultaneous estimation of longitudinal models with nested data structures, which occurs when couples are examined over several time points. Analysis and presentation of data will be in accordance with the CONSORT guidelines.

**Data monitoring**

A Data Monitoring Safety Board does not seem warranted, as we do not conduct a pharmacological study. Completeness of data will be checked after participation. Comments of the participants are used to improve data collection constantly. Data collectors meet regularly to exchange experiences and problems and to ensure adherence to protocol.

First interim results will be possible after T9, when the interventions are terminated.

**Potential harms**

As the current intervention is a psychological not a pharmacological intervention, no adverse effects are expected. However, participants are told verbally and in writing to contact study coordinators at any time if there are questions or any inconvenience. Throughout the study, a psychotherapist is on constant call for participants. Data collectors have contact details with them if requested by participants and are told to report unusual experiences to study coordinators immediately.

**Auditing**

The investigators organize workshops. Evaluations by participants and feedbacks from data collectors will be reported after each workshop. Investigators will collect and control audio recordings of home visits.

**Protocol amendments**

If substantial amendments will be needed, they will be notified to the internal Ethic Committees of the Philosophical Faculty of the University of Zurich. Non-substantial amendments will be recorded.

**Ancillary and post-trial care**
Participants can contact study coordinators if interested in further care. In this case an initial interview with a couple, child or individual psychotherapist will be sponsored by the study.

**Dissemination policy**

Data processing will be divided between investigators in accordance with their research focus and the authorship regulations. Results will be published in peer-reviewed scientific journals in accordance to international standards. Participants will be informed about results and conclusions.

**Discussion**

The TTP represents a critical phase in couples' lives going along with a higher risk for personal and interpersonal stress and a deleterious impact on health, the intimate relationship as well as child development. Many couples struggle during this stressful period and report a decrease in their individual and relational well-being. Both are significant predictors for child development. To support families at this critical stage we developed two couple-focused interventions, targeting enhancement of parents' relational skills and thus not only aiming to improve relational well-being but also coparenting skills, individual well-being and consequently child outcomes. With this study, we plan to investigate the role of relational skills for child development and the effectiveness of a low and high dose of a couple-focused intervention and if successful target a broader dissemination to ensure good relational, individual and child well-being after TTP.

**Study Status**

First participants enrolled on June 1st 2014. Recruitment for T11 has started in March 2019 and is planned to be completed June 30th 2020. Currently 234 participants have signed the informed consent form. This is protocol version 1.0 (02.09.2019).

**Abbreviations**

TTP = transition to parenthood; CCC-P = Couple Care and Coping for Parents programme; CCET = Couples Coping Enhancement Training; WOP = week of pregnancy; WAB = weeks after birth; YAB = years after birth;

**Declarations**

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We thank all our participants, our midwives, data collectors and coders.
Declaration of interests and funding

The authors declare that they have no competing interest. The intervention is a conglomerate of two different non-commercial relationship education programmes. CCET is developed by GB and owned by the University of Zurich. The Couple CARE programme is developed by Kim Halford and owned by the University of Queensland. The psychoeducational movie was developed by GB and VRA. The study is funded by the Swiss National Science Foundation (SNSF: grant numbers: 146775 and 173270, desk@snf.ch).

Availability of data and material

Data and materials will be made available upon request.

Authors contributions

GB is the principle investigator and obtained funding. GB, VRA, AM, MS, FM, PZ and AI participated in the study design. VRA, FM and CS are responsible for trial coordination. GB, PZ, FM, MS, AI, and CS drafted the manuscript. All authors gave feedback to earlier versions and approved the final manuscript.

Ethics approval, consent to participate and consent for publication

The investigation is conducted in strict agreement with the declaration of Helsinki and with the European Directive 95/46/EC on the protection of individuals and children with regard to the processing of personal data. We will further follow the guidelines for psychological studies of the Swiss Association for Psychology (SGP) and the ethical guidelines of the Federation of Swiss Psychologists (FSP). The study is approved by the Ethics Review Board of the Philosophical Faculty of the University of Zurich, Switzerland (approval numbers; 7.2.6, 18–12–2013).

All participants need to give written informed consent to participate in the study. Participants receive written study information before consenting. Personal verbal clarification will be given if required. Participants will be explicitly informed of their right to retract consent at any time without reasons or any negative consequences.

Consent for publication is not applicable due to the type of article.

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Figures
Figure 1

Mediation model of couple-focused interventions on child outcomes Notes. Theoretical model underlying this study.

Figure 2
### Project duration and participant timeline.

**Figure 3**

Schedule of enrolment, interventions, and assessments. Note. WOP = week of pregnancy, WAB = week after birth, YAB = years after birth

**Supplementary Files**

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