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Étude contrôlée non randomisée évaluant l'impact de lu2019“ Appui Parental ”, dispositif d'accompagnement précoce et intensif auprès de familles vulnérables : protocole de lu2019étude

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Research article

A non-randomized controlled study to assess the impact of the “*Appui Parental*”, an early and intensive support programme for vulnerable families: Study protocol

Étude contrôlée non randomisée évaluant l'impact de l'« Appui Parental », dispositif d'accompagnement précoce et intensif auprès de familles vulnérables : protocole de l'étude

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ABSTRACT

Introduction. – Early home visit programmes have been developed to help parents build an adequate relationship with their baby and to prevent child developmental delays and affective disorders. The “*Appui Parental*” programme is an intervention carried out by nursery nurses to provide intensive parental support to vulnerable families. Before extending this programme, it seemed necessary to evaluate its impact objectively.

Objectives. – The main aim is to determine the impact of the “*Appui Parental*” programme on the change in the child's symptoms. The secondary objectives are to evaluate its effects on mother-child interactions, self-assessed parental competence, perception of social support, primary caregiver's anxiety-depression symptoms, alliance with the nursery nurse, frequency of out-of-home placements, and nursery nurses' stress.

Method. – This non-randomized prospective multicentre study would include 44 families who receive the “*Appui Parental*” intervention for a one to 20-month-old child (intervention group) and 44 families with the same vulnerability criteria who receive care as usual by the maternal and child protection services (control group). The child, parents, mother-child interaction, nursery nurse-mother alliance, and nursery nurse's stress will be assessed at month one and month 18 after inclusion. Comparisons between groups will be performed.

Conclusion. – This study should provide the public authorities with objective data on this programme's impact and allow them to pursue its generalization. For professionals, the study should confirm the interest in close early parental support through home visits or should lead to rethinking some aspects of the programme.

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Abbreviations: CBCL, child behavior check-list; CDI, child development inventory; e-CRF, electronic case-report form; HV, home visit; IT-WAI-S, infant-toddler working alliance inventory-short version; MBI, Maslach burnout inventory; PANJO, health and attachment promotion of new-borns and young parents; PACOTIS, parental cognitions and conduct towards the infant scale; PSSQ, perceived social support questionnaire; SCL, symptom check-list; SCL-90-R, symptom check-list 90 revised; STPMI, services territorialisés de protection maternelle et infantile (Territorialized Services of Maternal and Child Protection).

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R É S U M É

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Introduction. – Afin de prévenir les troubles psychoaffectifs, les retards de développement et les troubles somatiques associés, plusieurs programmes de soutien parental précoce sous forme de visites à domicile ont été élaborés, notamment pour les familles dites à risque multiple. Ils ont pour objectif de soutenir la mise en place d'un environnement familial et de relations parent-enfant adaptés. En France, ce soutien parental précoce est pratiqué essentiellement par les services territorialisés de protection maternelle et infantile (STPMI). On observe cependant peu de programmes structurés ou d'interventions thérapeutiques à domicile spécifiques, et peu d'études ayant évalué leur efficacité. L'Appui Parental, action de soutien parental renforcé réalisée par des puéricultrices dans des familles vulnérables avec un enfant de moins de 3 ans, vise à soutenir de façon intense et prolongée les compétences parentales et la mise en place d'une relation d'attachement sécuritaire. Après environ quinze ans d'existence, et avant d'étendre cette action à d'autres territoires, une évaluation objective de son impact a été décidée.

Objectifs. – L'objectif principal est de déterminer l'impact de l'Appui Parental sur la symptomatologie de l'enfant 18 mois après le début de l'intervention. Les objectifs secondaires sont d'évaluer les effets de l'intervention sur le développement de l'enfant, les interactions mère-enfant, le sentiment de compétence parentale, la perception du soutien social, l'état anxiodépressif de la mère ou du soignant principal, l'alliance entre la mère et la puéricultrice, la fréquence de la judiciarisation des situations et enfin sur le stress des puéricultrices.

Méthode. – Cette étude prospective multicentrique inclut 44 familles bénéficiant d'un appui parental pour un enfant âgé de 1 à 20 mois (groupe intervention) et 44 familles répondant à des critères de vulnérabilité équivalents et qui bénéficient de la prise en charge habituelle proposée par le STPMI (groupe contrôle). Une évaluation du développement de l'enfant, de l'état psychologique des parents, de l'interaction mère-enfant, de l'alliance puéricultrice-mère et du stress du professionnel a lieu dans le mois suivant l'inclusion et 18 mois plus tard, à l'aide de questionnaires et d'un enregistrement vidéo d'un épisode de jeu mère-enfant. Les résultats à 18 mois seront comparés dans les deux groupes après ajustement sur l'état initial à l'aide d'une régression linéaire incluant tous les facteurs de confusion identifiés dans les analyses univariées comparant les deux groupes.

Discussion et conclusion. – Nous formulons l'hypothèse que les symptômes de l'enfant après 18 mois de suivi seront significativement moins importants chez les sujets ayant bénéficié de l'Appui parental (groupe intervention) en comparaison des sujets avec une prise en charge classique (groupe contrôle). De même, il est attendu que les autres tests aient des meilleurs résultats dans le groupe intervention que dans le groupe contrôle. Cette étude devrait apporter aux pouvoirs publics une meilleure visibilité sur les résultats que l'on peut attendre de ce dispositif et le cas échéant, en poursuivre la généralisation. Aux professionnels, l'étude devrait confirmer l'intérêt d'un soutien rapproché à domicile ou conduire à repenser certains aspects du dispositif.

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1. Introduction

1.1. Background and rationale

The aim of early interventions targeted to parents and infants with vulnerability criteria is to promote the development of adapted parent-child relationships and family environment. The attachment theory [1] postulates that to experience harmonious social and emotional development, young children need to develop an attachment relationship with at least one person ("the caregiver") who takes care of them consistently and continuously. The caregiver's responses to the child's behaviours guide the development of more or less secure attachment patterns. The attachment relationship quality influences the child's ability to regulate stress during alarm/distress situations [2]. It also influences the child's brain, social-emotional, cognitive and language development [3,4]. Prolonged separation from or frequent changes in primary caregiver affects attachment security, and can be a source of later psychopathology in the child [5]. The consequences can be the same when the caregiver produces inadequate and/or inconsistent responses, especially due to psychopathology or psychological fragilities [6].

Selma Fraiberg [7] was among the first to describe the effects of home visits (HV) on early attachment relationships between young children and their parents. Many countries subsequently introduced and validated parenting support programmes based on HV by health or early childhood professionals [8-10]. These pro-

grammes target mainly vulnerable families due to their economic insecurity and lack of personal and social resources [11]. They consist of structured short- or medium-term interventions to help parents supporting their child's emotional and behavioural development by working on their parenting skills and family functioning. The programmes vary greatly depending on the context, population, theoretical approach, and team involved [12]. According to McDonald et al. (2012) [11], HV interventions can be divided in two types in function of their intensity, scope and degree of prescriptiveness: interventions that follow detailed programme manuals and provide comprehensive care through an extensive HV schedule, and interventions that focus specifically on the parent-child interactions and are less prescriptive.

Several literature reviews and meta-analyses demonstrated the effectiveness of these early parenting support programmes on mothers' anxiety and depression, maternal sensitivity, parent-child interactions, and child development [13-17]. However, studies on the effectiveness of different intervention modalities (i.e. professional involved, presence or not of targeted objectives, starting date, HV frequency and duration) have yielded conflicting results [11,13-15,17,18]. Several authors highlight the importance of supervision for the involved professionals [19].

In France, mother and child protection services (*services territorialisés de protection maternelle et infantile*, STPMI) provide parenting support and prevention from pregnancy initiation and during the child's early years, based on risk criteria identified by professionals. Parenting support is mainly provided through HV

by nursery nurses [20]. A 2018 survey among STPMI professionals highlighted several limitations of these interventions: lack of time (with rarely more than one intervention per month), absence of theoretical references, variability in objectives for each professional, lack of specificity in the objectives, and insufficient support through supervision sessions [21].

Despite some initiatives inspired by Fraiberg's pioneering model [22], there are few structured programmes or specific therapeutic home interventions. Moreover, few studies evaluated the effectiveness of early support. Yet, it is essential to verify whether the existing programmes achieve their objectives [11]. Providing public authorities with a better visibility would also encourage the generalization of programmes with the most beneficial effects for the child and their family [20,21].

To date, in France, the CAPEDP study [23] is the only large study on the effect of HV conducted by psychologists in vulnerable families from the third trimester of pregnancy until the child's second birthday. Its results did not show any additional benefit of the programme compared to usual care. However, it found a significant effect on depressive symptoms at month 3 post-birth in some subgroups: mothers with only few depressive symptoms at inclusion, mothers with a present child's father, and mothers with higher education [24].

Currently, the PANJO project (health and attachment promotion of new-borns and young parents) is proposed to primiparous families who declare themselves isolated. It offers interventions at home from the prenatal period until month 6 or 12 post-birth to promote the development of a secure attachment and the use of medical and social services. Nursery nurses are led to consider their actions with the parents not within an educational framework, but in a relational and reassuring mode. Supervision is carried out to provide nursery nurses with sufficient psychological support [25].

In 1998, the Hérault department council set up the "Appui Parental" programme in one of its STPMI to promote the child's optimal development in families identified as vulnerable. The ultimate objective was to reduce the need of out-of-home child placement or to prepare for possible placement together with the parents [26]. The aim of this support programme, intended for parents of 0 to 3-year-old children in vulnerable situations, is to provide frequent and prolonged support for parenting skills and establishing a secure attachment relationship. After 15 years of operation and its extension to all the STPMI of Montpellier, an objective evaluation of the effectiveness of the "Appui Parental" programme seemed necessary, especially due to its high cost in terms of personnel and before deciding on its further extension.

2. Objectives

The main objective is to determine the "Appui Parental" programme impact on the child's symptom changes at month 18 after the intervention start, relative to the initial state. The intervention group will be compared to a control group that receive the usual STPMI care.

The secondary objectives are to evaluate the intervention effects on the child development, mother-child interactions, self-assessed parental competence, perception of social support, anxiety and depressive symptoms in the main caregiver, degree of alliance with the childcare provider, frequency of judicialization of situations (child's placement or court order for educational measures) and finally, the stress of the involved health professionals.

Our main hypothesis is that changes in child's symptoms at month 18 will be significantly greater, after controlling for the initial state, in the intervention than in the control group. Similarly, other tests should give better results in the intervention group.

2.1. Trial design

This is a prospective, multicentre, comparative, controlled, non-randomized study to evaluate a health programme during a follow-up period of 18 months.

The study is designed and carried out in accordance with the principles of the Declaration of Helsinki, the Law of Bioethics, the Law of Computing and Freedom, and Good Clinical Practice. The protocol was written in accordance with the SPIRIT guidelines.

3. Method

3.1. Study setting

The study is conducted among families supported by the STPMI. Families were recruited at 15 sites: the five agencies covering Montpellier and offering the "Appui Parental" programme (intervention group); and ten volunteer agencies that provide only usual assistance (control group). Monitoring and data collection are carried out by STPMI physicians and two clinical psychologists/researchers. The various assessments are performed at the STPMI or the families' homes.

3.2. Eligibility criteria

3.2.1. Inclusion criteria

Families with a 1 to 20-month-old child who are eligible to receive the "Appui Parental" programme or care as usual (in the absence of this programme) were included. These families had to meet vulnerability criteria leading to presumed or proven difficulties in meeting their children's needs (Table 1). The criteria were identified from the literature and the clinical experience of the STPMI teams. At least one major criterion was required, due to their significant association with early childhood disorders or maltreatment [27–31].

In case of no major criterion, three minor criteria (two of which had to be related to the mother) were required, identified as other risk factors related to the environment, the child or the parent [32]. The number of 3 minor factors was chosen because several studies have shown that the risk factors potentiate. In particular, families with 2 to 4 risk factors would be twice as likely to meet incompletely the emotional and cognitive needs of the child [33]. Finally, the family must be affiliated with or benefit from the social welfare system.

3.2.2. Non-inclusion criteria

The non-inclusion criteria were: mother with psychosis, need of immediate child protection, legal measures in progress for the child, follow-up not possible for 18 months, parent(s) not speaking French, family followed by the STPMI already for > 3 months, parent(s) under guardianship or curatorship.

3.3. Consent and confidentiality

Full information about the study was provided to the parents by the STPMI physician, who delivered an information notice. The parents signed the informed consent form after sufficient time for reflection. The signature of both parents was systematically sought. However, as the targeted families were vulnerable, often with an absent father, and as the study did not involve any risk for the child or the parents, the ethics committee (CPP Sud-Méditerranée IV, reference 13 10 06 2013 A01298-37) authorized the collection of only one signature to avoid excluding the families with the most difficulties (inclusion bias).

Table 1
 Criteria of vulnerability.

Criteria of parental vulnerability	Major	Minor
Possible associated child development disorders	- Parent's psychiatric disease	- Parent's psychological difficulties
	- Addiction	- Parent's immaturity
	- Conjugal violence	- Social and family isolation
	- Parent receiving adult disability allowance for intellectual disability	- Parent with severe somatic disease
	- History of placement of one parent	- Partner's psychiatric disorder
	- History of placement concerning one of the child's siblings	- Marital conflict situation
	- Behavioural problems	- High socio-economic precariousness
	- Feeding difficulties without organic aetiology	- Non-supportive or dysfunctional family environment
	- Polymalformative syndrome or severe physical/mental disability	
	- Very/extreme pre-term baby	
	- Severe somatic disease	

To preserve confidentiality, a number was assigned to each family. The STPMI team in charge of the family's follow-up was not informed of the content of the data collected.

3.4. Interventions

3.4.1. Description of the "Appui Parental" intervention

The "Appui Parental" programme is designed for parents of young children aged 0 to 3 years, when the parents present vulnerability criteria. Its specificity lies mainly in its contract-based formalization, its frequency, its theoretical basis-attachment theory and the supervision of the professionals.

Families are identified through the usual STPMI system. After the "Appui Parental" team validates the selection, a contract is signed for 6 months, renewable until the child is 3 years old. No financial contribution is required and the parents can put an end to the programme whenever they wish. This contract agreement system should increase the parent(s)' commitment. The STPMI physician carefully monitors the situation during the programme. The contract is renewed every 6 months until the child is 3 years old. The parent(s) can reconfirm their interest in the support and the nursery nurse can adapt the intervention to their needs and expectations. The follow-up of the physician also allows for the readjustment, intensification or termination of the "Appui Parental" in case of an alert.

The intervention systematically includes one or two HV per week, lasting 2 to 3 hours. The interventions are based primarily on the attachment theory principles, as well as on the observation and support of parent-baby interactions. This observation is based on works that have described early interactions and elaborated some tools such as the Bobigny early interaction observation grid [34,35]. The priority is to support the security and skills of the main caregiver through an alliance, so that the caregiver can improve his/her availability for the child, identify his needs and provide adjusted answers. The priorities for action are also guided by the needs expressed by the main caregiver. The intervention is indeed multimodal and identify any need of the mother or the baby requiring the intervention of other professionals.

During the weekly visits, the nurse listens to the main caregiver, validates his/her emotions, difficulties and skills, and takes into account his/her priority needs, ranging from nursing to practical daily problems, and expectations. She also supports functional parent-baby interactions and helps the caregiver understand the behaviours of the baby. This relationship can be established around bathing, eating or bedtime moments. Through moments of direct interaction with the child, the nurse encourages the establishment of playtime, helps the parent to confront it, providing some support or a role model. She represents a reference adult who offers the child, through weekly meetings, an experience of adapted

interactions, with sensitive answers. Once or twice per week, the nurse also takes the mother and child to group activities (parent-child groups, baby-swimming, psychomotricity classes, and walks), which represent another way of supporting the mother-child bond and promoting their socialization.

The system is implemented by nursery nurses dedicated exclusively to this programme and who have a flexible schedule to allow frequent and regular HV. They are linked to the multidisciplinary team of a STPMI, especially to the physician in charge of the service. Most of them have been trained to or are familiar with the attachment theory. Additionally, 2 hours weekly group supervision sessions ensure a process of on-going education. These sessions are led by a child psychiatrist or psychologist who is not linked to the STPMI. They provide emotional support and strengthen reflective skills, by exploring situations and explaining the interactions between the nursery nurses' emotions, feelings, and behaviours and those of the families.

3.4.2. Choice of comparator

The "Appui Parental" programme will be compared to the services usually offered by the STPMI: paediatric and nursery nurse consultations; and/or 45-90-minute HV by STPMI nursery nurses once a week for three weeks after birth, and then less frequently over a variable length of time, depending on the situation; and/or HV (1-3 times per week) by a social and family intervention worker.

3.5. Outcome measures

The Table 2 describes the main characteristics of the tools chosen for the evaluation.

3.5.1. Primary outcome

The primary outcome is the child's symptomatology, measured by the change in the Symptom Check-List (SCL) score [28,36] between inclusion and month 18 post-inclusion.

3.5.2. Secondary outcomes

The secondary outcomes are:

- the child development and symptomatology, assessed at inclusion and month 18 post-inclusion with the Denver Developmental Screening Test (DDST) [41,42], and at month 18 with the Child Development Inventory (CDI) [39,40] and the Child Behavior Check-list (CBCL) [37,38]. The CDI and CBCL cannot be used at inclusion because the children are too young, but are essential tools to compare the child's condition between groups at month 18;
- the parents' psychological status at inclusion and month 18, including the parents' psychopathology assessment with the

Table 2
 Tools description.

Tools	Type	Objective	Description	Psychometry
Symptom check-list (SCL) [36]	Self-questionnaire completed by the parent	Quantifies the most common psycho-functional symptoms in children aged 2 months to 3 years (frequency, duration, intensity) over the past four weeks	<ul style="list-style-type: none"> - Six domains: sleep, eating, digestion, behaviour, fear-timidity and separation - 6 sub-scores ranging from 1 to 5 - Overall score averaged over the 6 sub-scores - Impact of the child's symptoms on the family assessed with a score from 1 to 5 	Validated in a clinical population and a general control population [28]
Child behavior check-list (CBCL) 18 months-5 years [37]	Self-questionnaire completed by the parent	Assesses aspects of the emotional and behavioural life of children aged 18 months to 5 years	<ul style="list-style-type: none"> - 99 questions coded with a 3-point scale - Score in 7 domains: emotional reactivity, anxiety-depression, somatic complaints, sleep problems, avoidance, attention problems, aggressiveness - Score for internalized disorders: emotional reactivity, anxiety-depression, somatic complaints and avoidance - Score for externalized disorders: attention problems and aggressiveness - Total score - Language assessment to determine a delay in sentence and vocabulary development. Only the average sentence length scale will be used 	Widely used in English-speaking countries Validated in many countries [38]
Child development inventory (CDI) [39]	Self-questionnaire completed by the parent	Assesses the developmental delay or progress of children aged 15 months to 6 years	<ul style="list-style-type: none"> - 270 items concerning observable skills in everyday situations - Developmental age in 8 domains: socialization (40 items), autonomy (40 items), gross motor skills (30 items), fine motor skills (30 items), receptive language (50 items), learning letters (15 items) and numbers (15 items) 	Translated into French [40]
Denver II developmental screening test [41]	Completed by the physician	Assesses social contact, fine motor, language and motor skills of children aged 2 weeks to 6 years	<p>Coded from direct observation of the child's skills. It is presented in the form of a table specifying for each of the 4 domains assessed the elements expected according to the child's age. The normal individual variability for each test is represented by a rectangle, ranging from 25 to 90% of success. Items that can be completed by 75-90% of children but are failed are called cautions; items that can be completed by 90% of children but are failed are referred to as delays. A normal score means no delay in any domain and no more than one caution; a suspect score means one or more delays or two or more cautions</p> <ul style="list-style-type: none"> - 90 items and 9 domains: somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobias, paranoid traits and psychotic traits - 5-point Likert-type scale, ranging from 0 (not at all) to 4 (extremely yes) - Provides a Global Severity Index (GSI), a Symptom Diversity Index (SDI), and a Positive Symptom Distress Index (PSDI) 	One of the oldest and easiest to use developmental screening tools Translated into French [42]
Symptom check-list 90 revised (SCL-90-R) [43]	Self-questionnaire completed by the parent	Assesses general adult psychopathology	<ul style="list-style-type: none"> - 90 items and 9 domains: somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobias, paranoid traits and psychotic traits - 5-point Likert-type scale, ranging from 0 (not at all) to 4 (extremely yes) - Provides a Global Severity Index (GSI), a Symptom Diversity Index (SDI), and a Positive Symptom Distress Index (PSDI) 	Translated and validated in French [44]
Parental cognitions and conduct towards the infant scale (PACOTIS) [45]	Self-questionnaire completed by the parent	Measures parents' perceptions about their parental role and their involvement in certain parenting practices	<ul style="list-style-type: none"> - 4 dimensions: parental self-efficacy, perceived parental impact, parental hostile-reactive behaviours, and parental over-protection 	French language scale used in Quebec, with good psychometric properties
Perceived social support questionnaire (PSSQ) [46]	Self-questionnaire completed by the parent	Assesses the type of social support received, the sources of that support, the number of people providing it, and the perceived quality of the support	<ul style="list-style-type: none"> - 10-point Likert-type scale, higher scores indicating greater use of the behaviours described. The Perceived parental impact subscale items are reverse coded - 4 dimensions: esteem support (comforting, listening in difficult moments), material or financial support (direct assistance when necessary), informational support (advice or suggestions from others) and emotional support (reassuring, restoring confidence) - Responses on a 5-point Likert-type scale. For each type of support, the scale assesses how many people provide it, who these people are (family, friends, colleagues, specialists) and whether the subject is satisfied with this support - Total score Availability = sum of responses on "how many" items - Total score Perceived satisfaction = sum of responses on satisfaction items 	Widely used French language scale

Table 2 (Continued)

Tools	Type	Objective	Description	Psychometry
Infant CARE-index [47]	Coded by the researchers	Evaluates mother-child interactions based on 10-minute free play recorded using a standardized supply of age-appropriate toys	- Coding of 7 aspects of interactional behaviour: facial expressions, vocal expressions, body postures, expressions of affection, role turns, control, and activity choice - Uses three items for the mother (reactive, controlling, and unavailable) and four for the child (cooperative, compulsive, oppositional, and passive) to obtain a score from 0 to 7 for each item - Coding was done in a blinded fashion: the film of the mother-child game was coded by two psychologists trained in this tool and who did not know the family	Used in many different countries with different cultures and practices Good psychometric properties [48]
Maslach burnout inventory (MBI) [49]	Self-questionnaire completed by the parent	Evaluates the burnout syndrome	- 22-question questionnaire, with responses on a 7-point scale (from "never" = 0 to "every day" = 6) - Explores three dimensions: burnout, depersonalization, and personal fulfilment and provides a score for each dimension. A high score on the first two dimensions and a low score on the last one indicate burnout	Good psychometric properties [50] Translated and validated in French [51]
Infant-toddler working alliance inventory-short version (IT-WAI-S), parent and professional versions [52]	Self-questionnaire completed by the parent, and by the nursery nurses	Evaluates the therapeutic alliance	- 12 questions and 4 dimensions: professional-parent bonding (3 questions), professional-child alliance (3 questions), "positive" dimension of goals and tasks (3 questions), and "negative" dimension of goals and tasks (3 questions with answers reversed from the others) - Responses on a 7-point scale, 3 of which are defined (1 = strongly disagree; 4 = moderately agree, 7 = strongly agree) - Questions slightly modified to adapt to the context of the "Appui Parental" context: replacement of "consultations" by "meetings", and of "consultant" by "nursery nurse"	The WAI is widely used in English language studies [53] It has been translated into French and adapted to the context of early parent-child consultations [52]

Symptom Check-list 90 Revised (SCL-90-R) [43,44], their sense of parental competence assessed with the Parental Cognitions and Conduct Towards the Infant Scale (PACOTIS) [45], and their perception of social support with the Perceived Social Support Questionnaire (PSSQ) [46];

- the mother-infant interactions, at inclusion and month 18, measured using the Infant CARE-Index [47,48];
- the alliance between nursery nurse and family, at inclusion and month 18, measured with the Infant-Toddler Working Alliance Inventory-Short version (IT-WAI-S), adapted from the Working Alliance Inventory [52,53], completed by the parents and the nursery nurse;
- the nursery nurses' stress, at inclusion and month 18, assessed with the Maslach Burnout Inventory (MBI) [49-51].

The following sociodemographic data were collected at inclusion: child's gender and date of birth, number of siblings, sibling rank, parents' marital status, ages, education levels and employment status, perceived social protection benefits, accommodation type, child's place of residence, and childcare arrangement type. Moreover, the following data were collected during the follow-up: other assistance and care received by the family, occurrence of a placement or a court order for education measures. A clinical examination of the child was performed at inclusion and month 18.

3.6. Participant timeline and procedure

Inclusions occurred from April 2014 to May 2021. The Table 3 and Fig. 1 present the data collected at the different stages and the procedure.

To promote the recruitment of families, several support actions were carried out for the STPMI teams participating in the research. A meeting was organized in each agency with the nursery nurses and physicians to present the protocol, identify possible obstacles, and provide synthetic working documents that could be used daily (e.g. list of the eligibility criteria, how to approach the families).

During the study, regular meetings took place to remind the teams of the study procedures and review potential inclusions. When the nursery nurses felt that they were having difficulties in proposing the research to the families, the research psychologists offered to contact the families directly.

To minimize the number of people lost to follow-up, the nursery nurses were contacted every three months to ensure that there had been no significant change in the family situation (i.e. family moving outside the department). If the family did not attend the initial or final evaluation, the psychologist contacted the STPMI physician to evaluate the best relaunch strategy. If the mother refused the assessment at the STPMI office, a meeting at home was proposed, or the questionnaires were filled in by telephone as last resort.

To maintain the STPMI teams' motivation, meetings were organized by the research team with all or each STPMI team on topics related to early childhood and attachment.

3.7. Monitoring

In accordance with the Good Clinical Practices, a clinical research officer mandated by the promoter was responsible for guaranteeing the patients' protection, the respect of the protocol and legislation, and the integrity of the collected data. The level of monitoring was low because of the absence of risk for the individuals included. Consents were checked as they were signed. A monitoring visit by the investigator and psychologists was conducted every 4 months for the first year and then every 12 months.

4. Data management and analysis

4.1. Data management

An electronic case-report form (e-CRF) was developed using the Ennov Clinical software to control data quality at entry. This software complies with the FDA recommendations. The connection is via a username and password unique to each specific user and

Table 3
Content of the visits.

	Visits				
	To be completed by	Time needed to complete the questionnaire	V0 (inclusion)	V1 (within 1 month after inclusion)	V2 (18 months after inclusion ± 1 month)
Study information	STPMI physician		X		
Collection of informed consent	STPMI physician		X		
Inclusion/non-inclusion criteria verification	STPMI physician		X		
Clinical examination	STPMI physician	50 min		X	X
DDST					
Tests					
Child					
SCL	Mother	20 min		X	X
CDI	Parents	20–30 min			X
CBCL	Parents	15–20 min			X
Parents					
SCL 90-R	Parents	15 min		X	X
PACOTIS	Parents	5–10 min		X	X
PSSQ	Parents	4–6 min		X	X
Mother-child interactions					
CARE-Index	Mother (play)	Play: 10 min; Psychologist coding: 45 min		X	X
Alliance					
IT-WAI-S mother	Mother	5 min		X	X
	Nursery nurse	5 min		X	X
IT-WAI-S nursery nurse					
Professional stress					
MBI	Nursery nurse	5–10 min		X	X

STPMI: *services territorialisés de protection maternelle et infantile* (mother and child protection services); DDST: Denver developmental screening test; SCL: symptom check-list; CDI: child development inventory; CBCL: child behavior check-list; SCL 90-R: symptom check-list 90 revised; PACOTIS: parental cognitions and conduct towards the infant scale; PSSQ: perceived social support questionnaire; IT-WAI-S: infant-toddler working alliance inventory-short version; MBI: Maslach burnout inventory.

gives access only to the data of the centre's user. An audit trail function is included to allow the supervision and traceability of all actions by all users. The encrypted data are transmitted to the data management centre via a secure internet connection. The data manager performs additional tests to confirm the data completeness, consistency and reliability during the patients' recruitment and follow-up. Once quality assurance procedures have been completed, the database will be locked.

4.2. Statistical methods

4.2.1. Sample size

One study [54] on 49 young children (3 to 30-month-old) who consulted for functional or behavioural problems investigated SCL score changes between before and after the therapeutic intervention. The mean SCL scores were 2.22 ± 0.45 before the therapeutic intervention, and decreased by 17% to 1.84 ± 0.52 after the intervention ($P < 0.001$).

Based on these data, it was estimated that 40 children per group were needed, assuming a first-species risk of 5% and power of 90% in the case of a two-sided alternative hypothesis. The percentage of participants lost to follow-up was estimated at 10%. Therefore, 44 children were included in each group.

4.2.2. Statistical analyses

The statistical analysis will involve all patients for whom data on the primary outcome at baseline and month 18 are available (full analysis set). Baseline characteristics will be reported using mean and standard deviations (or median and inter-quartile range) for continuous variables and frequencies and proportions for categorical variables. These baseline characteristics will be compared using standard tests.

For the main outcome (SCL score change between inclusion and 18-month visit), comparisons between groups will be performed

using multiple linear regression including all confounding factors identified in univariate analysis comparing the two groups. The effect size will be estimated using the Cohen's d. Values of d range from 0.01 to 2, and values from 0 to 0.3, > 0.3 to 0.7, and > 0.7 are considered a small effect, medium effect, and large effect size. Because of the children's young age at inclusion, the SCL scores at month 18 will be compared in the two groups after adjustment to the initial score.

For the secondary outcomes (i.e. DDST, CBCL, IDE, SCL-90-R, PACOTIS, PSSQ, IT-WAI-S, MBI, number of placements), a multiple linear regression will be used for each score including the variable group and all confounding factors.

Correlations between scale scores will be assessed using the Spearman rank correlation coefficient with 95% confidence intervals. Missing data will be managed by multiple imputations. The statistical bilateral significance threshold will be set at 5%. Statistical analyses will be performed using SAS version 9.4 (SAS Institute, Cary, North Carolina).

5. Discussion – conclusion

Preventing difficulties in early interactions and promoting the attachment process are crucial for child development. Parenting support programmes with HV by early childhood professionals have been developed to address this issue. Mothers are interested in this programme type that they value due to the prolonged follow-up, preferential and trust-based relationship with a professional, intervention flexibility, parental guidance and psychological support (Saias et al., 2018). However, in France, these programmes are still rare, have limitations, and have been rarely studied. This study should allow assessing the impact the "Appui Parental" intervention, designed to provide reinforced support to vulnerable families.

This study has limitations. Randomization was considered but not chosen because of the ethical difficulties raised by the

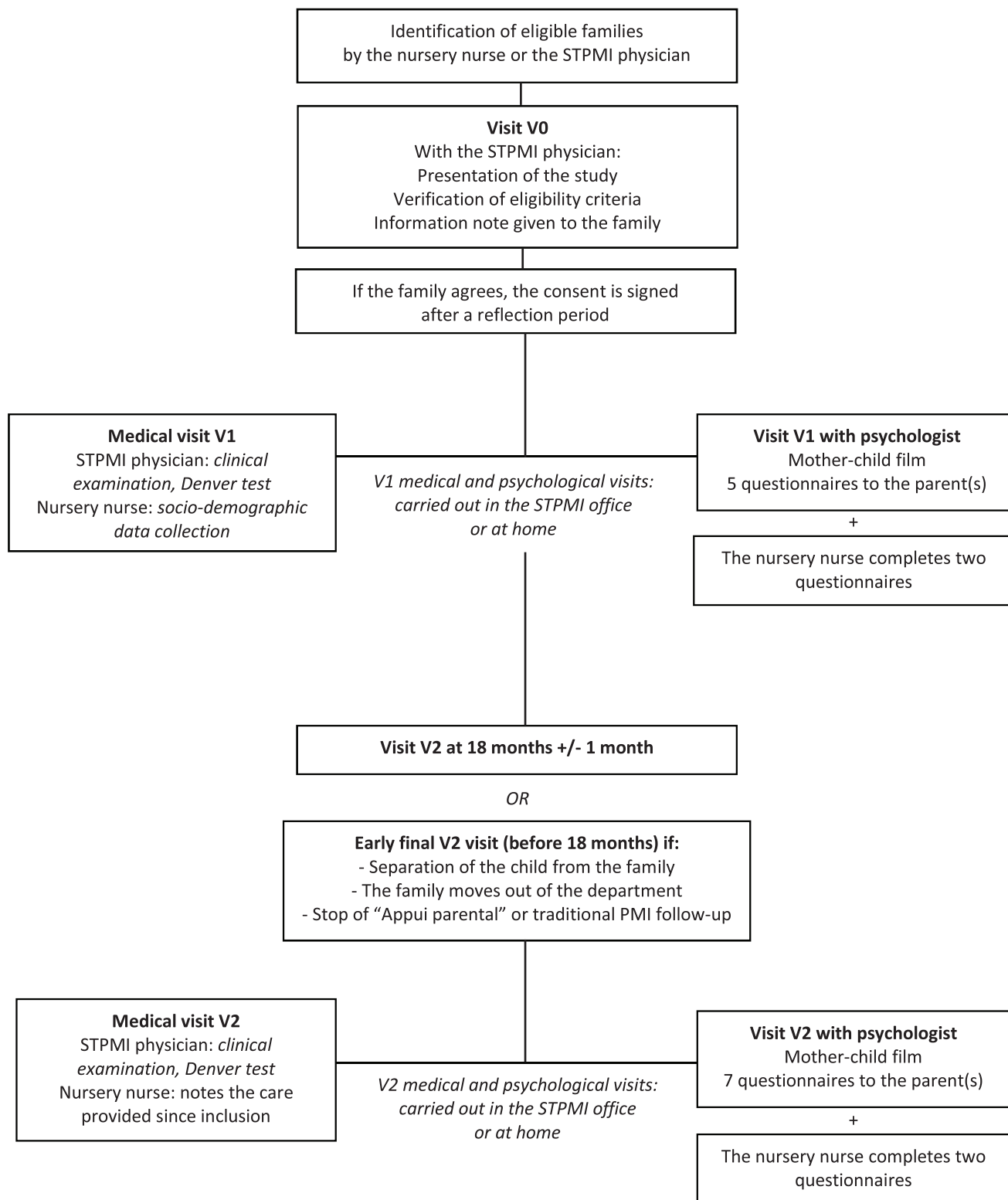


Fig. 1. Study protocol.

STPMI teams: this would have meant not offering to some vulnerable families the “Appui Parental” programme when available in the agency, which was not acceptable. Similarly, a cluster randomized controlled trial design was not selected because the programme had already been introduced in all the Agencies of the city (n=5) before the study was designed, with traditional care being provided by the other Agencies of the department (n=10).

However, to compensate the non-randomization, the trial was controlled. This will allow the comparison of the two groups on all collected data and the identification of possible confounding factors. The proportion of subjects remaining in the study and the satisfaction of the users evaluated through the IT-WAI-S parent version will be considered. The planned multivariate analysis will take confounding factors into account.

The family recruitment faced difficulties, particularly for the control cases, due to several factors: work overload by the STPMI teams; families' reluctance towards research and evaluation, fearing care drop-out by proposing the study; a lesser engagement in the study by some teams because they were not involved in its design (particularly the agencies where the control cases were recruited); and especially, STPMI teams' fear of being evaluated and judged through measures linked to the research. These difficulties required extending the initially planned inclusion period and special support to the teams. A possible bias will have to be discussed during the analyses, because families with the most difficulties may have been less frequently included. Moreover, the vulnerable families that make up our population are at risk of drop-out, with therefore a possible high rate of loss of contact.

This study should allow the objective description to the public authorities of the benefits that can be expected from this programme and if these are confirmed, allow them to pursue its generalization. For professionals, the study should confirm the value of close support at home or lead to reassessing some aspects of the programme. The challenge is to promote a more secure parent-child attachment in the most vulnerable families, better child development, and avoid children's out-of-home placements whenever possible.

Disclosure of interest

The authors declare that they have no competing interest.

Ethical approval

The study was designed and carried out in accordance with the principles of the Declaration of Helsinki, the Law of Bioethics, the Law of Computing and Freedom, and Good Clinical Practice. The study protocol was approved by an ethics committee (CPP Sud-Méditerranée IV, reference 13 10 06 2013 A01298-37), the ANSM (national agency of medication safety and health products, B131453-31, 21/03/2014) the 15/01/2014 and by the national committee authorizing data collection (CNIL 1585321 v0, 07/05/2012).

Consent to participate

Written informed consent was obtained from all participants prior to their inclusion in the study.

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