DISORDERS AFFECTING THE HEALTHY DEVELOPMENT OF INFANTS AND YOUNG CHILDREN

PhD Thesis

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List of Abbreviations

ESPGHAN – The European Society for Pediatric Gastroenterology Hepatology and Nutrition

IECMH - Infant and Early Childhood Mental

IMH – Infant Mental Health

PDF - Paediatric Feeding Disorder

PFD-T - Paediatric Feeding Disorder who require Tube feeding

1. Introduction

The teaching of the biopsychosocial model has gained widespread use in medical education in recent decades. The approach to disease has previously focused on pathophysiology and biology, in which the psychological and social effects on health and disease status have been ignored (Engel 2015). The bio-psycho-social model (Engel 1977) is based on general systems theory (Bertalanffy 1968), which examines the whole in a dynamic system, its relationships and interactions, rather than one-sided causality (Bertalanffy 1972). The bio-psycho-social model provides a comprehensive theoretical framework for interpreting diseases as it takes into account not only biological causes, but also psychological factors and social effects (Túry 2005). The application of the biopsychosocial approach to clinical practice enables clinicians to follow patients from the molecular to societal level, taking into account patient's subjective experiences, which are essential for an accurate diagnosis and an expected effective treatment outcome. (Borrell-Carrió 2004). According to the model developed by Sarafino and Smith (Sarafino and Smith 2011), the human body is integrated into interrelated biological and psychological systems, and each system is subdivided into additional subsystems. Humans come into direct contact with the social systems of the world; moreover, systems can influence any other systems. Based on this systems approach, the development of the infant and young child can also be examined as part of its interactions with the environment. Following the perinatal events, the new-born arrives in the family around it, where the new situation initiates a series of changes taking place in several directions in space and time. The family is a living, open system, characterized by striving for balance, regulated by positive and negative feedback. Our medical diagnostic thinking is aided by knowledge of Bronfenbrenner's (Bronfenbrenner 1979) human ecological model, which views the child and the family around it in a broader multiple system. Systems are denoted as microsystems, mesosystems, exosystems, and the macrosystem. The microsystem is the most basic level. Persons, institutions and other circumstances directly surrounding the child at a given time directly affecting the development can be included here. Mesosystems involve environmental systems that directly affect the child. In this system, the elements of the microsystem are interconnected. External conditions belonging to exo-systems have an indirect effect on the child's daily life and development. At this level, the child's immediate physical environment and the quality of its relationships may be shaped by social circumstances that are mediated by parents. The

macro-system is a broader cultural, historical situation, and a set of other social expectations and opinions, which fundamentally influences the child's life situation and development In his bioecological model, Bronfenbrenner (1994) describes the development of the self in interaction with its environment, highlighting the importance of the direct effect of proximal factors. By contrast, the effect of indirect, distal factors predominantly manifest at later stages of development (Bronfenbrenner and Ceci 1994, Danis and Kalmár 2011). If the condition of the young child justifies it, we can supplement our questions by thinking along this system during the detailed medical history, which provides a well-traced basis for managing the problem. The early childhood developmental pathway influences a child's psychological, emotional and social development. Furthermore, how it enters into a complex series of interactions with the physical and social world, and what capacity it has to interact with and affect the environment (Mares 2011). In order for a child to develop, it needs an optimal interaction with the systems around it, during which the child and the environment change. This process is described by Sameroff in his theory of transactions (Sameroff 2010), according to which the child is an active participant in the relationship with the environment, during which a series of interactions take place leading to changes. Development is thus manifested in the result of this interaction, namely in the development of the abilities of the developing young child and in the realization of its capacities. The unified theory of development proposed by Sameroff (2010) represents an understanding of human growth through integrating four models of development, such as personal change and the contextual, regulation, and representational models. Personal change delineates the progression of competencies from infancy onwards. The contextual model is important to outline the multiple sources of experience which further or constrain individual development. The regulation model includes a dynamic systems approach to the relationship between person and context, and is also referred to as transactional model, where the development of a child is the result of a continuous dynamic interaction between the child and their experiences in social settings (Sameroff 2010). Thus, the unified theory of development introduced by Sameroff (2010) provides a solid basis for the understanding of the developing child within its environmental context in clinical practice.

In order to apply the biopsychosocial framework to clinical practice in the field of pediatrics, we familiarize ourselves with the child's history in terms of life circumstances.

Moreover, we acknowledge that relationships play a central role in managing the problem. Further, our diagnostic and therapeutic tools cover all three areas: medical, psychological, and social. Figure 1. presents the enter of intervention.

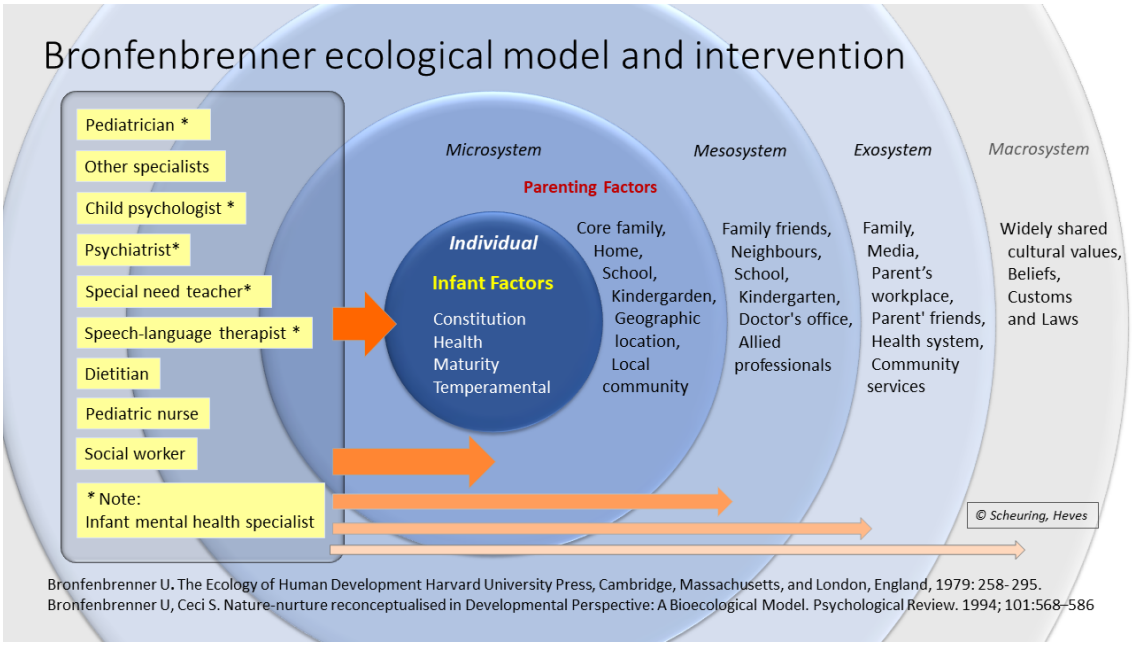

Figure 1. Bronfenbrenner ecological model and intervention. Based on the work of Bronfenbrenner (Bronfenbrenner 1979, Bronfenbrenner and Ceci 1994)

How can infant mental health fit into the line of theories and models outlined above, and why may the disorders affecting the healthy development of infants and young children be viewed in a broader sense in this framework? Infant mental health is a research and clinical field focusing on the understanding of the factors that promote and ensure optimal development and the implementation of intervention methods. It also seeks to alleviate the physical, emotional and social risk factors of some infants / young children and their families (Mares 2011). Furthermore, it follows Bronfenbrenner ‘s ecological model in its interventions targeting the developing early infants and young children. Additionally, the elements of Sameroff’s theory including interrelationships and the consideration of interactions and their effects, are important aspects of IMH’s work.

Zeanah (Zeanah and Zeanah 2009) highlights that IMH is a complex, interrelated nature of human development and its deviations beyond the capabilities of any particular discipline. It is likely that the field of IMF will remain pluralistic, a subspecialty within a

number of different disciplines, rather than an integrated and distinct discipline itself (Zeanah and Zeanah 2009 p.6).

The definition of infant mental health was defined by the Zero to Three Infant Mental Health Steering Committee according to the characteristics of the child as follows:

„A toddler's ability to experience, regulate, and express emotions, build close and secure relationships, and explore the environment and learn. All of these abilities are best realized within the context of the caregiving environment that incorporates family, community, and cultural expectations for young children. Developing these skills is synonymous with healthy social and emotional development (Zero to Three, 2001)"(Zeanah et al, 2005).

According to Zeanah and Zeanah, IMH is the clinical science of early age experience. (Zeanah and Zeanah 2018 p.17). IMH deals with ages 0-3, and Infant and Early Childhood Mental Health, IECMH covers early childhood from 0-5 years. Our research concerns the 0-3 age group. Therefore, it is within the framework of IMH, emphasizing its peadiatric implications.

To what extent does the interdisciplinary scientific approach to infant mental health contribute to broadening the horizons of our everyday paediatric practice. How does this inform our clinical work when a parent reports a symptom of a young child as to whether to interpret it as an abnormal symptom. In many cases, simple cause and effect relationships do not provide a clear explanation for the young child's symptom(s), and additional treatment issues may arise. However, there can also be insecurity and mistrust in the parent if they do not get a reassuring answer to the problem.

That is why we consider it important to look at the various behavioural manifestations of young children, with which the parents visit the health care system, being integrated into a complex system. In practice, for example, observing a parent-infant interaction in an examination or eating situation. The problem can be managed accordingly with the multidisciplinary scientific knowledge of infant mental health. In order to take into account psychosocial factors and other environmental factors in addition to the medical background, it is necessary to expand and apply our knowledge in this direction, and to cooperate with other professions.

Infant and early childhood is an age range among the periods of life span. It has been the subject of numerous international and domestic research. (Danis and Kalmár 2020).

Our present study focuses on the assessment of the factors leading to the development of regulatory disorders in early childhood, as well as their association with various pathological conditions. We analyze the topic of regulatory disorders through the publication ”Recognizing Early Regulation Disorders in Pediatric Care” (Scheuring et al, 2021) and the questions of tube feeding through the publication „Pediatric tube-feeding: An agenda for care improvement and research” (Hopwood 2021).

In the course of our research, there has been a growing demand on the part of families to seek support for their children with eating and sleeping disorders, wich we have provided with an independent outpatient clinic (Scheuring and Szabó 2020, Scheuring et al, 2018). For young children with more severe eating disorders, hospitalization is sometimes required.

1.1. Recognizing Early Regulation Disorders in Pediatric Care

Regulation disorders are already apparent in infancy. The For Healthy Offspring Project was the first Hungarian study aimed at building an effective model for screening and examining the prevalence and complex (medical and psychosocial) background of classic behavior regulation disorders (excessive crying, feeding, and sleep problems) in infancy.

Emotional and behavior regulation disorders in infancy and toddlerhood are quite frequent, with an occurrence of 5-20% in a normal population. (Zeanah and Zeanah 2009, Mindell et al 2010, Wurmser et al, 2001, McDermott et al, 2008, Corbett et al, 2004). Primary or classic regulation disorders (“the classic triad”), such as excessive and persistent crying and sleep and feeding disorders, are already seen in early infancy and can also be recognized and diagnosed in primary care (Zeanah and Zeanah 2009, Herman and Le 2006, Bernard-Bonnin 2006, Carter and Wrede 2017, Keren 2016, DC: 0-5TM 2016).

Other regulation disorders, such as strong defiance and temper tantrums, aggression, excessive clinging, intense separation anxiety, lack of interest in play activities and the like, appear from two years of age onward. In most cases, the cumulative combination of somatic, interactional and psychosocial factors leads to problematic behaviors (Zeanah and Zeanah 2009). According to the framework of developmental psychopathology (Hinshaw 2008), in most cases, the cumulative combination of somatic, interactional, and psychosocial environmental risk factors and a lack of significant protective factors leads

to problematic behaviors associated with several types of early mental health problems (DC: 0-5TM 2016). Similar to other early childhood mental health problems, the background of regulation disorders is also assumed to be influenced by complex mechanisms, whereby the individual physical and psychological characteristics of the parents and the children, their common early history (pregnancy, birth, early care), the actual parent-child interactions, and the developing relationships serve as key proximal mediators of more complex distal factors, such as the sociodemographic situation, family structure, stressful life events, and social support. Naturally, the manifestation of certain problems can depend on other moderating factors, such as the age, sex, and temperament of the child (Zeanah and Zeanah 2009, Papousek et al, 2008). The transactional developmental theory ⁽Sameroff 2010) and the Bronfenbrenner Model (Bronfenbrenner and Ceci 1994), can help to explain the formation of the problems.

This clinical area is specifically located at the juncture of medicine, psychology, and education, and it therefore requires an interdisciplinary approach and handling. The risk factors that compromise childhood development, parent-child interactions, and family functioning and the protective factors that support resilient development are important issues to be borne in mind in both research and clinical practice (Masten and Monn 2015). Since most of the relevant literature comes from small-sample studies, continued research is needed with larger samples to further explore the clinical significance of regulation disorders (De Gangi 2017). In the meantime, the findings as a whole highlight the paucity of evidence about this group of infants and the need to prioritize them for research and clinical work (Keren 2018).

The study, screening, and treatment of early childhood mental health problems have a decades-long history in international practice, but the investigation of such disorders, as well as the related prevention and intervention activities, remains an understudied area in Hungary. To date, only a few national private and public initiatives have expressed interest in developing this area. The For Healthy Offspring Project, initiated by the Heim Pál National Pediatric Institute in Budapest, was the first Hungarian research to establish an effective hospital model for screening and to examine the prevalence of emotional and behavior regulation disorders in early childhood (0-3 years) and the significance of different risks and protective factors behind them (Scheuring et al, 2021, Scheuring et al, 2012, Scheuring et al, 2011, Németh et al, 2017, Németh et al, 2018, Németh et al, 2018). We developed a complex model to screen for regulatory problems in early childhood. We

present the methodology of our study as a screening model for recognizing early regulation disorders in pediatric care.

Our aims were to (1) introduce the model of our screening program and our large-sample hospital research, (2) report the occurrence of major regulation disorders (excessive crying, sleep and feeding problems) in our sample, and (3) report associations between regulation disorders and other examined medical diseases. In addition, we also show the main results on prevalence of medical and psychosomatic complaints, the comorbidity between them and the relationship between medical examinations and parental questionnaire reports.

We hypothesized that (1) the prevalence of regulation disorders in our Hungarian sample is similar to that of other countries, (2) the associations between excessive crying, sleep and feeding disorders are strong, and (3) these regulation problems may also be moderately associated with other diseases

1.2 Paediatric feeding disorder (PFD), and paediatric feeding disorder who require tube feeding (PFD-T).

Paediatric feeding disorder (PFD

Based on the framework of the World Health Organization *International Classification of Functioning, Disability, and Health*, a unifying diagnostic term is proposed as follows: "Pediatric Feeding Disorder (PFD), defined as impaired oral intake that is not age-appropriate, and is associated with medical, nutritional, feeding skill, and/or psychosocial dysfunction" (Goday 2018 p.125). By including functional limitations, this diagnostic criteria should enable researchers and practitioners to promote inclusion of all relevant disciplines in treatment planning, to better identify the needs of heterogeneous patient populations, and to facilitate the use of common terminology essential to further research, health care policy, and clinical practice. A proposed PFD diagnostic criterion is based on the following: medical, nutritional, feeding skills, and psychosocial dysfunction. The handling of PDF requires an interdisciplinary team involving feeding specialists, child psychologists, other physicisians, nurses and social workers (Goday 2018).

PFD**,** can have wide-ranging and serious consequences for the health and wellbeing of the child and their family (Hopwood N, 2020).

A special group of infants need tube-feeding. Tube-feeding at home (also known as home enteral nutrition) can help to maintain growth in many complex feeding cases (Krom H et al, 2019, Wilken M 2018), but can have side-effects for children and significant psychosocial impacts on carers and children. (Enrione EB, 2005, Nelson KE 2015). An agenda for care improvement and research article presents an agenda to improve the care and wellbeing of children with paediatric feeding disorder who require tube feeding (PFD-T). PFD-T requires urgent attention in practice and research. Priorities include: routine collection of PFD-T data in health-care records; addressing the tube-feeding lifecycle; and reducing the severity and duration of disruption caused by PFD-T where possible. This work should be underpinned by principles of involving, respecting and connecting families (Hopwood et al, 2021).

There are multiple, complex pathways to paediatric tube-feeding, as documented in ESPGHAN guidelines. (Braegger et al, 2010). Common indications include prematurity, congenital heart disease, cerebral palsy, cystic fibrosis, neurodevelopmental disabilities, metabolic disease and cleft palate. (Fleet et al, 2020). Tube-feeding may also be required while children are critically unwell or after surgery. (Morton et al, 2019). The Feeding Tube Awareness Foundation (Feeding Tube Awareness Foundation 2020) identified over 350 conditions that can warrant tube-feeding, which is viewed as incomplete.

The UpToDate presents in detail nutritional assessment and indications for enteral nutrition in children (Fleet et al, 2020)

Knowledge of paediatric tube-feeding care practices is fragmented, lacks a coherent agenda and is difficult to synthesise. Tube-feeding is managed in many different parts of the health system, confounded by weak and inconsistent prevalence data. Prevalence is often estimated to be around 1–4 per 100 000 (Edwards et al, 2016) but can be as high as 83–92 per 100 000, (Krom et al, 2019) although there are good reasons to think actual rates are higher.(Krom et al, 2019). This is indicative of the fact that tube-feeding lacks visibility in the health system and clinical data collection: it is a category void.

In research, paediatric tube-feeding tends to be addressed with reference to particular conditions or diseases (Banhara et al, 2020, Craig and Scambler 2006, Bicakli et al, 2019, Pedersen et al, 2004, Sleigh 2005, Sleigh 2004), but some studies have examined tube-feeding across more than one clinical domain (Guerriere et al, 2003, Spalding and McKeever 1998). Children who tube-feed represent a heterogeneous group with multiple

co-morbidities. (Sharp, Jaquess, Morton, et al. 2010). Tube-feeding has been conceptualised differently by the many specialities working in the area. (Sharp et al, 2010, Bryant-Waugh 2013, Lukens and Silverman 2014). A recent consensus paper proposed a definition of a PFD that encompasses, although is not limited to, children who require tube feeding: impaired oral intake for more than 2 weeks that is not age-appropriate, and is associated with medical, nutritional, feeding skill and/or psychosocial dysfunction. (Goday et al, 2019). The US Centers for Disease Control and Prevention recently announced that PFD will be a stand-alone diagnostic code in the 2021 edition of the International Classification of Disease (Pedersen 2020).

The recognition of PFD as a discrete diagnosis is an essential foundation for paediatric tube-feeding research. Within PFD, tube-feeding is one approach to treatment (which itself incorporates variation, for example in the kinds of tube used). Some, but not all, children with PFDs will be tube-fed. Of children who meet the criteria for PFD however, our research has identified that those who require tube-feeding are a clinically distinct group who have unique health care and support needs over and above that associated with their PFD diagnosis.

We propose that PFD-T be defined as 'children with PFD who require tube-feeding for more than two weeks'. This definition keeps PFD-T solely as a subgroup within PFD, with the 2-week duration differentiating children with PFD who may require short-term/acute tube-feeding (such as for a hospital admission with gastroenteritis). Keeping PFD-T within PFD means that a transition to oral feeding, while an important milestone, will not represent a 'cure' or the end of feeding difficulties for the child and family, and that PFD-T must be addressed using the same holistic approach to the child and family as outlined by the definition of PFD itself (Hopwood et al, 2020).

We propose PFD-T for use in research and care improvement purposes. This is not suggested as a diagnostic category, but as a means of identifying and collecting data about a discrete group that has a meaningful, shared basis to be considered as such (tube-feeding), despite different reasons for tube-feeding being needed (evident in the functional basis of the definition of PFD above) (Hopwood et al, 2020).

PFD-T requires urgent attention from the linked perspectives of care improvement and research, recognising and understanding outside the silos of conditions that lead to it. (Puntis 2012). Better understanding of, and care in relation to, PFD-T could make a

positive difference across many child health domains including chronic disease and disability.

To contextualise this agenda, we offer statements from mothers who are parents of children who have tube-fed.

2. Objectives

1. The aim of our study focuses on the factors influencing early childhood development, is carried out in close collaboration with practical work and research. In the course of our pediatric work, new challenges are revealed to us, which require a solution to the pathological symptoms of the developing infant / toddler thought to be a medical problem.
2. The aim of our study is to assess the conditions influencing healthy development, to explore the possibilities of early detection of negative effects, and to apply our knowledge in the care of young children, in collaboration with their families.
3. We also consider it important to record and process the experiences and results of our practical work through our knowledge of infant mental health, which can serve as a good practice in the care of young children aged 0-3.
4. Our aim was to present the Healthy Offspring Project, the first Hungarian research to screen and investigate the prevalence and complex (medical and psychosocial) background of classic behavioral disorders in infancy (excessive crying, feeding, sleep disorders).
5. Our aim was to investigate the cumulative combination of somatic, interactional, and psychosocial environmental risk factors in most cases within the framework of developmental psychopathology and to investigate that the lack of significant protective factors leads to problematic behavior associated with several types of early mental health problems.
6. Our aim was to show that the background of regulatory disorders, like other early childhood mental health problems, is presumably influenced by complex mechanisms, such as individual physical and mental characteristics of parents and children, common early history (pregnancy, childbirth, early care), actual parent-child interactions and emerging relationships serve as key proximal mediators in more complex distal factors such as sociodemographic status, family structure, stressful life events, and social support. Naturally, the manifestation of certain problems can depend on other moderating factors, such as the age, sex, and temperament of the child.

7. Our aim to show that risk factors that compromise childhood development, parent-child interactions, and family functioning, and tje protective factors that support resilient development, are important in both research and clinical practice.
8. Our aim was to develop a complex model to screen for regulatory problems in early childhood. We present the methodology of our study as a screening model for recognizing early regulation disorders in pediatric care. The study, screening, and treatment of early childhood mental health problems have a decades-long history in international practice, but the investigation of such disorders, as well as the related prevention and intervention activities, remains an understudied area in Hungary.
9. Our aim was to introduce the model of our screening program and our large-sample hospital research.
10. Our aim was to report the occurrence of major regulation disorders (excessive crying, sleep and feeding problems) in our sample
11. Our aim was to report associations between regulation disorders and other examined medical diseases.
12. In addition, we also show the main results on prevalence of medical and psychosomatic complaints, the comorbidity between them and the relationship between medical examinations and parental questionnaire reports.

Hypotheses

1. Our hypothesis that the prevalence of regulation disorders in Hungary is similar to that of other countries.
2. Our hypothesis the associations between excessive crying, sleep and feeding disorders are strong.
3. Our hypothesis that these regulation problems may also be moderately associated with other diseases

3. Material and Methods

3.1 Early Regulation Disorders

Families of 0- to 3-year-old children with eating or sleeping problems or extreme crying from 3 departments of the Heim Pál National Pediatric Institute in Budapest and neighboring areas were included in this study. Data were collected from July 2010 to June 2011 in a cross-sectional design study (Scheuring et al, 2021).

We obtained information about early childhood regulation disorders from 4 sources, including questionnaires, medical examinations, and individual and small group consultations.

The model of the screening process, the data collection, and the administration of the For Healthy Offspring project are shown in **Figure 2**.

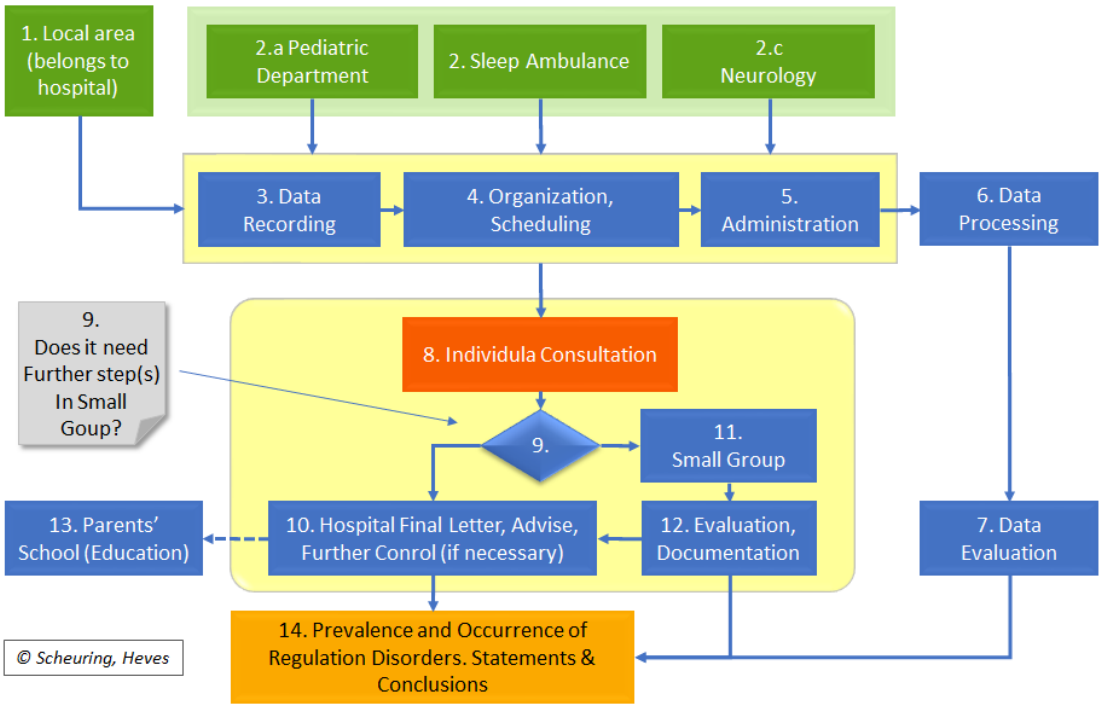

Figure 2. The model of the data collection and the analyses in the For Healthy Offspring projec (Scheuring N, Danis I, Papp E, Benedek P, Németh T, Gulácsi Á, Szabó, L. 2021, Scheuring N, Danis I, Németh T, Papp E, Czinner A. 2012)

During the research period, we recruited from among all families with children under 3 years of age (n=1855) within 3 departments of the hospital, and 580 families volunteered

to participate. This represents a response rate of 31.4%. During the same period, we also collected data (n=584) with the help of health visitor nurses in neighboring areas. The nurses mainly administered the questionnaires to the families with whom they visited spontaneously during their work or who visited them during their consulting hours. Thus, both subsamples were specific and selective in terms of willingness to participate and motivation to share concerns. We hypothesized that hospital rates underrepresent the real incidence of regulation disorders, while area rates overrepresent them.

In summary, in our sample, the inclusion criterion was age under 3 years among those children who visited the 3 hospital departments or lived in neighboring areas. There were no exclusion criteria. Data collection could be biased by some methodological issues such as willingness to participate and motivation to share concerns.

Although our sample was not representative, it was nevertheless adequately heterogeneous in all relevant sociodemographic characteristics (**Table 1**).

Questionnaires were given to parents (n=1164) by doctors and nurses working in 3 departments (Pediatric, Sleep, and Neurology) of the Heim Pál National Pediatric Institute (n=580) and also by health nurses and general practitioners in local areas (n=584). Mothers responded in 1133 cases.

Medical examinations and/or diagnostic evaluations were performed in 619 cases.

When completing the questionnaire, the parents were offered a complex screening program (a longer medical consultation) in our hospital if any of the most common behavior regulation disorders were present in the child. A total of 183 families took part in this complex diagnostic evaluation.

Afterwards, 35 parent-infant dyads also took part in small-group consultations. For some families, individual consultations and psychotherapy were recommended with the support volunteer hospital or other institutional professional.

The process and professional content of the Screening Program are seen in **Figure 3**.

Table 1. Demographic variables*.

Variable	Sample of mothers who filled in the questionnaires (N = 1133)	Subsample where medical examinations were also conducted (n = 619)
	Percent/Mean (SD)	Percent/Mean (SD)
Child's gender		
Boy	52.7%	55.2%
Girl	47.3%	44.8%
Child's age (months)	15.3 (10.8)	15.02 (11.07)
0-2	9.7%	12.1%
3-5	14.9%	15.9%
6-8	10.1%	8.5%
9-11	10.6%	10.3%
12-17	16.0%	15.4%
18-23	13.2%	12.0%
24-36	25.4%	25.7%
Number of children in the family	1.7 (0.9)	1.7 (0.9)
No siblings	52.7%	52.4%
1 sibling	35.5%	35.8%
≥ 2 siblings	11.8%	11.8%
Oldest	58.3%	57.6%
Second	31.6%	31.6%
Multiple	10.1%	10.8%
Age of Mother (years)	32.0 (5.1)	31.68 (5.26)
≤ 25	10.5%	11.9%
26-30	25.6%	25.1%
31-35	40.0%	40.3%
36-40	20.2%	19.4%
≥ 40	3.7%	3.3%
Married/in common-law marriage	93%	90.7%
Maternal education		
Maximum elementary or skilled worker	17.7%	20.6%
High school	34.9%	34.0%
Postgraduate/College degree or more	47.3%	45.4%
Employed	66.2%	65.2%

* Frequencies for valid answers. The proportion of missing values is 0-5%.

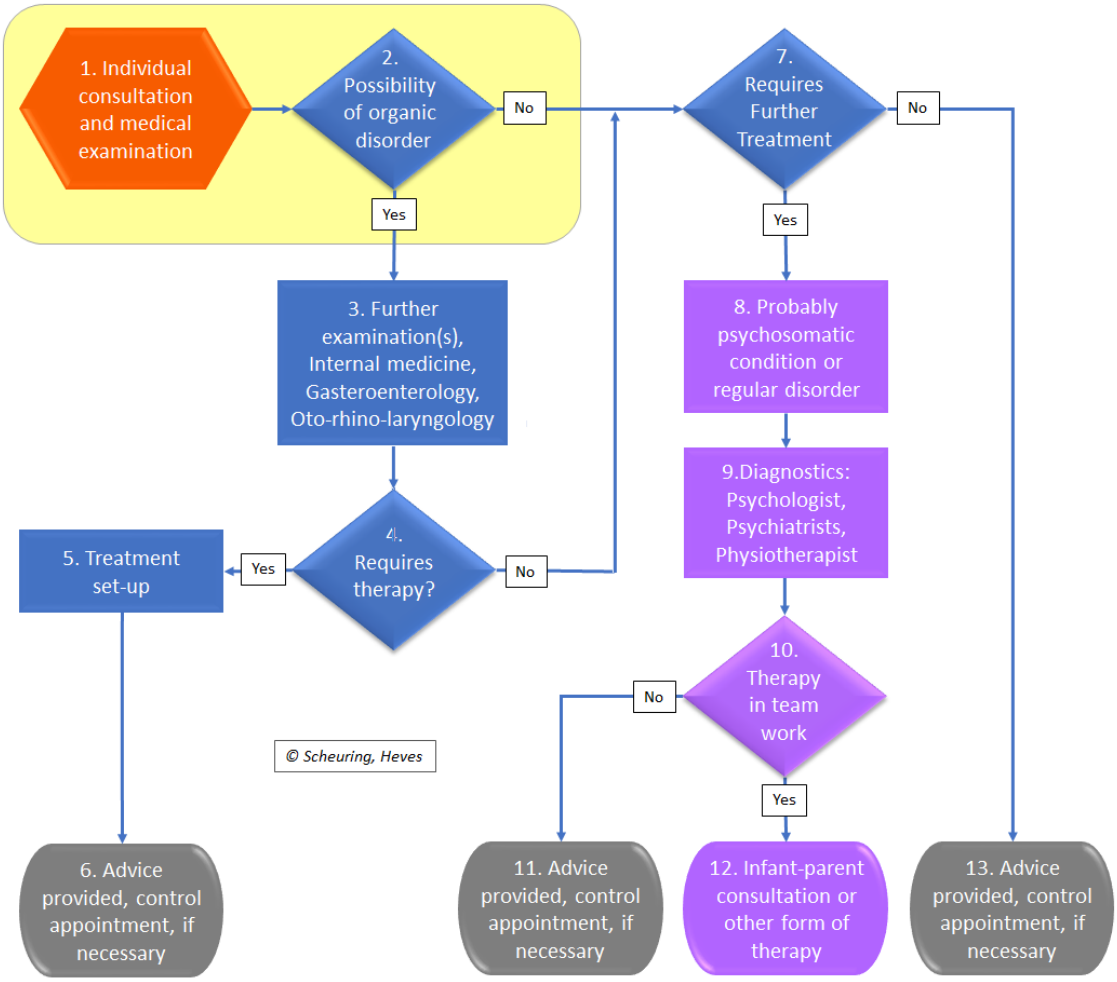

Figure 3. The process and professional content of the Screening Program

(Scheuring N, Danis I, Papp E, Benedek P, Németh T, Gulácsi Á, Szabó, L. 2021, Scheuring N, Danis I, Németh T, Papp E, Czinner A. 2012)

The Screening Program: Diagnostic Evaluation

Medical Consultation

Medical consultation (performed by NS and EP) consisted of a focused, detailed history taking that was followed by a physical examination (Figure 4). During the physical examination, healthy somatic, motor, and psychosocial developmental signs were carefully considered. In most cases, both parents were present when the child was examined; however, in a few cases, only the mother was present. The consultation normally lasted 1 h.

History taking started with the discussion of the symptom(s) that the parents had concerns about, and it was followed by general pediatric questions. To obtain broader knowledge

of circumstances, certain aspects of the child's psychiatric history (birth circumstances, pregnancy, perinatal period, early sensory-motor and mental development, family sociodemographic characteristics) were also included. In all cases, the primary consideration was to determine the organic causes of the symptoms. If no physical abnormalities were found, we assumed the causative effect of psychosocial factors.

In medical settings, the child's symptoms are the focus of investigation but paediatricians need to be mindful of the parents as well. In other words, in paediatricians' clinical work the infant is treated but parents are also a focus of attention and support. The meeting between parents, baby and paediatrician is unique. The child displays symptoms with changes in behaviour and parents interpret them to paediatricians. The transfer of this information can be difficult and confusing. A lot depends on parents' interpretation of the infant's symptoms and on the infant's physical and mental state, along with other factors.

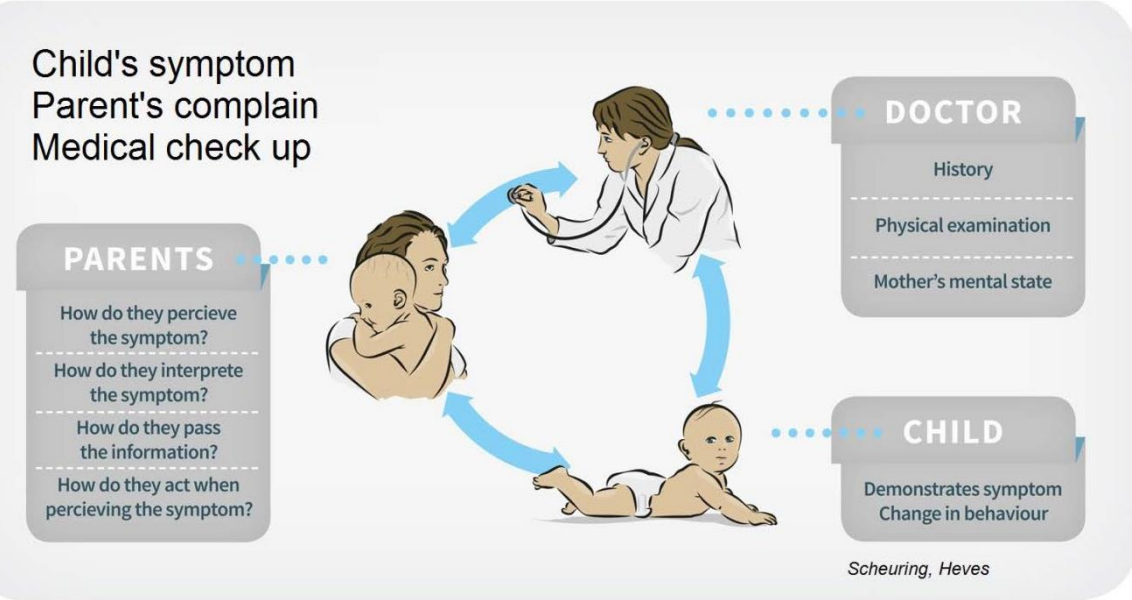

Figure 4. Infant and parent in medical setting an Infant Mental Health Approach (Scheuring 2017)

In paediatric practice, diagnostic methods and therapy generally focus on organic conditions but, in many cases, especially in regulation disorders (e.g., problems of feeding or sleeping, extreme crying, etc.) a bio-psycho-social approach is required to adequately understand the presenting difficulties (Tóth et al, 2017). It can be frightening for parents when the baby's behaviour changes, so they consult the paediatrician. It is helpful if the

paediatrician has basic mental health skills to recognise how the interaction between parent and infant can contribute to abnormal symptoms in the baby and, in turn, how this may alter how a parent perceives and communicates about their infant (Hinshaw et al, 2009). Paediatricians need to listen carefully about the specific problem parents and baby are presenting and provide relevant information to parents in a sensitive and supportive way (Committee on Psychosocial Aspects of Child and Family Health 2009).

Diagnostic Evaluation of Organic Causes, Differential Diagnosis

The results of the first consultation determined the subsequent diagnostic steps. Diagnostic evaluation of the organic causes was performed depending on the presence of abnormal findings. Examinations were performed at the Pediatric Department as an outpatient service and included laboratory tests and radiological imaging tests. In some cases, specific examinations were performed by a gastroenterologist, neurologist, otorhinolaryngologist, ophthalmologist, or cardiologist. An obstructive sleep apnea symptoms test and, in cases of indeterminate symptoms of the infant or the presence of apnea, polysomnographic monitoring combined with esophageal pH monitoring was performed (by PB) at the Sleep Ambulance by Somnoscreen Plus (SOMNOmedics, GmbH, Randersacker, Germany). The following symptoms of unspecified/unexplained origin, usually with no underlying medical condition, were found: periodic breath-holding spells or strange breathing sounds, change of skin tone, loss of consciousness, loss of postural tone, and seizure. A complex motor evaluation of the infant was completed by a physiotherapist.

In cases of medical illness, our work was based on general pediatric diagnostic steps. We had more difficulty diagnosing early behavior regulation disorders. The International Classification of Diseases, 10th Revision (ICD-10), which is used in Hungary, does not include clear directions about early childhood regulation disorders. In the differential diagnostics of regulation disorders, we relied on the principles of the German system, as described by Hédervári-Heller (Hédervári-Heller 2008) in Hungarian and German, although it is not widely used in Hungary. Moreover, we greatly profited from reviewing the classification criteria of the Diagnostic Classification of Mental Health and Developmental Disorders of Infancy and Early Childhood – Revised (DC: 0-3R)

(Diagnostic classification of mental health 2005), which was not used in Hungary at that time.

Small Group Consultation

As long as no organic abnormality was found, part of the sample was offered a small-group consultation. These consultations took place in the presence of the parents (or only the mothers) and the infants on 2 occasions, each lasting 90 min. The consultations were conducted by a pediatric psychotherapist (TN) with the participation of psychologists and psychiatrists from the hospital. During the small-group consultations, the following aspects were spontaneously observed: (a) infant's developmental level and the quality of his or her playing activity; (b) quality of the parent-infant interactions; (c) emotional reactions between the parents and their moods while together; (d) parent-infant attachment patterns based on the balance between exploration and attachment behaviors; (e) infant's attitude toward the parents and the professionals in attendance; and (f) ambience of the consultation meeting. At the end of the second meeting, the experiences were discussed with the families in a private meeting, and individual therapy for the parents or parent-infant consultations were offered if necessary. As professionals worked together in a team, they decided by consensus if regulation problems were present and whether additional care was needed due to psychosocial, relationship, or interaction difficulties. In many cases, the 2 small-group consultations were sufficient to resolve mild regulation difficulties.

Measuring Instruments

Questionnaires

A questionnaire package was specifically designed for this study. In our edited basic questionnaire, the parents were asked in detail about their family background, housing and job circumstances, their financial status, their health, health-related and psychological characteristics of the pregnancy and the birth of the examined infant, the newborn period, breastfeeding and early care, the infant's physical and mental condition, and his or her behavioral characteristics. We then focused on the 3 main areas of regulation disorders. Detailed questions were asked about each topic to determine if the infant was affected by intense crying and restlessness, feeding and weight gain difficulties, or sleep disorders.

Most of the questions were closed-ended, discrete questions with 2 or more possible answers, or Likert-type scale items, usually with 5 levels. Only the "other" questions were open ended. A pilot study was conducted to ensure that the questions were well understood by the respondents and could be answered easily and reliably. We were not able to measure internal consistency because these questions were single items and did not form scales. In this article, we used only the socio-demographic information and some Likert-type questions on early regulation (crying, sleep, and feeding).

Medical Diagnoses

The diagnoses determined in course of medical examinations and during individual and small-group consultations (see the detailed description of the Screening Program above) were included in our database.

3.2 Tube feeding

In the course of our research, a special group, the group of children fed by the probe, also came into view during hospital admissions. The assessment and management of tube fed children is integrated into the interdisciplinary medical care of the newly set up Early childhood Eating and sleeping disorders Outpatient Clinic (Scheuring et al, 2018, Scheuring and Szabó 2020). The experiences and results gained during the multidisciplinary care of children provided an opportunity to join an international program. Specialized team of outpatient clinic, methods and activitities are shown in Table 2.

Priorities

Paediatric Feeding Disorder who require Tube feeding (PFD-T) care improvement and research should address five priorities, summarised in Table 3. Routine and standardised collection of data regarding PFD-T in health-care records and data collection is crucial. The absence of this currently compromises opportunities to: gauge prevalence, monitor progress, measure outcomes and correlate these with other health, social and demographic variables. Care improvement, health service resourcing and economic modelling all depend on robust data. Routine documentation in clinical records will also better enable data linkage, randomised trials and meta-analyses addressing PFD-T. PFD-T, in general,

can be conceived in terms of three phases: initiation of tube-feeding, thriving while tube-feeding, and either tube weaning or transition to long-term tube-feeding (weaning is not possible for all).

Table 2. Multidisciplinary team – methods and activitities of Early Childhood Feeding and sleeping disorders Outpatient Clinic.

The specialized members of multidisciplinary team	**Methods and activities**
Pediatrician / Infant mental health specialist	The medical background – detailed pediatric examination and further investigations if necessary
Other specialties (if they needed): • Gastroenterology • Neurology • Sleep Clinic • Physiotherapist • Other	
Child psychologist	The psychological background – psychological diagnostic consultation and/or the developmental psychologic examination
Speech-language therapist.	Chewing and swallowing skills, sensory problems
Dietitian	Dietitian consultation if it is needed.
Special needs teacher/ Infant mental health specialist	Supporting the feeding events for the families by special nurses. In these cases, the families spend about 2-3 hours in the Clinic.
Pediatric nurse	There is an opportunity for non-structured observation and video recording of the feeding interaction as well.
Administration and data tracking	The assessment process and the documentation is determined by a pre-established concept developed by team members and represented on flowcharts.

These are distinct but not isolated from one another. Failure to support and plan for thriving while tubefeeding and eventual tube-weaning can cause significant anxiety for families, tube-feeding dependency and unnecessary delays weaning (Hopwood et al, 2020, Krom et al, 2019, Wilken et al, 2018, Edwards et al, 2016, Wright et al, 2011). Tube weaning should be addressed from the beginning of tube-feeding in all children who are expected to restore oral feeding (Trabi et al, 2010). At tube initiation, a plan covering the timing, method and team for weaning is recommended. (Dunitz-Scheer et al, 2009).

Table 3 Priorities for care improvement and research in paediatric feeding disorder requiring tube-feeding (PFD-T)

Area	Priorities arer perspective	Clinical care perspectíve
Recognition and data collection	Approaching care and communicating in a way that recognises the importance of PFD T as a distinct experience within PFD especially its connections with other aspects of the child and family's health	- Ensuring PFD T data are collected routinely in healthcare records, identifying standardised data points in the tube feeding lifecycle - Using these data to rneasure and understand variability, equity and change in healthcare practices, resources and outcomes, within and across services
Phase 1 Tube initiation	- Ensuring falies engage with tude feeding as indicated, to ensure safe, adequate growth and nutrition for their child - Reducing distress for children and families regarding nasogastic tube insertion and gastrostomy insertion	- Safely reducing tube feeding prevalence - Routine screening and investing risk and protective factors for parent stress and anxiety - Pathways to second and third phases, including a documented tube exit plan when appropriate
Phase 2 Thriving while tube feeding	- Enhancing education and support for families, lncorporating healthcare and psychosocial domains with a focus on optimising physiological progress, enabling joy during mealtirnes as quickly as possible, enabling children and their families to participate in preferred activities and psychological support for parents (Banhara et al 2020, Sharp et al 2020) - Enabfing social support and connection for children who are tube fed and their siblings, parents and others delivering care, partícularly by addressing stigmatisation (Banhara et al 2020, Sharp et al 2020)	- Identifying and avoiding unintended cornplícations - Joint decision making with families around transition from nasogastric tubes to gastrostomy as appropriate (Syrmis et al 2020) - Pathways to the third phase, with clear progression towards tube weaning or meaningful goals when tube feeding is life long (Syrmis et al 2020, Wright et al 2011)
Phase 3 Tube weaning	- Supporting tube weaning to happen as soon, quickly and safely as possiblé (Wilken et al 2018, Syrmis et al 2020, Trabi et al 2010, Dunitcz-Scheer et al 2009) - Ensuring families feel safe and confident in the timing of and approach to tube w.eaning	- Supporting tube weaning to happen as soon as quickly and safely as possible (Wilken et al 2018, Syrmis et al 2020, Trabi et al 2010, Dunitcz-Scheer et al 2009) - Better understanding tube dependency and tube weaning pathways including psychologically informed alpproaches (Gardinet et al 2014)
Transitioning to long term tube feeding	- Supporting children and their immediate families to thrive when tube feeding is long term - Identifying and progressing towards meaningful endpoints or goals (e. g. participation in education,employnent, transition out of paediatric care), - including through research, community advocacy, and workplace innovation	- Attuning interactions between clincians/care providers and families to a long term tube feeding experience when tube removal is not possible

(Hopwood et al, 2020)

Poor awareness of tube weaning may negatively impact the quality of care for children who are tube fed, included infrequent use of tube exit plans. (Syrmis et al, 2020, Gardiner et al,2014). Relatedly, the timing of transition from an nasogastric tube to a gastrostomy is variable, as is guidance on when is optimal to do so (Syrmis et al, 2020). Evidence of what constitutes high-quality care across the tube-feeding lifecycle is urgently needed, recognising the importance of multidisciplinary and interdisciplinary approaches that actively include parents and caregivers as experts in the lived experience of caring for children who tube feed. (Sharp et al, 2020, Sharp et al, 2017).

Statistical Analysis

Quantitative analyses were performed using IBM SPSS Statistics 20.0 software package (IBM, Armonk, NY, USA).

For the descriptive statistics in this article, we calculated prevalence distributions and for examining associations between regulation problems and other health conditions, we ran crosstabs (χ^2-tests) in the cases of diagnoses (yes/no; 1/0 categorical variables) and Mann-Whitney tests in the cases of questionnaire data (Likert-type items, see **Table 4**).

Table 4. shows the significant differences between means and standard deviations of answers to questions in parental questionnaire in subgroups where different regulation disorders were diagnosed or not diagnosed.

Table 4. Diagnoses of regulation disorders in medical examinations and differences between maternal answers in questionnaires. In diagnosed cases, parents report making it more difficult and problematic to care for their children.

Medical diagnoses: Excessive crying, restlessness	Not Diagnosed *n*; Mean (SD)	Diagnosed *n*; Mean (SD)	*z*- statistics in Mann-Whitney tests
How can you characterize your child by strong prolonged crying when he/she was a little baby? (5-point Likert scale: *values 4–5*)	*n* = 507 2.16 (1.10)	*n* = 92 2.90 (1.28**)**	z = –5.205; *p* < 0.001
According to your observations, how much was your child crying or how fussy was your child in the previous two weeks? (*more than 1 hour*)	*n* = 486 2.83 (1.12)	*n* = 90 3.31 (1.28)	*z* = –3.227; *p* = 0.001
How could you soothe him/her when he/she was crying? (5-point Likert scale: *values 1–3 for low self-confidence*)	*n* = 505 4.32 (0.77)	*n* = 92 3.97 (0.90)	z = –3.641; *p* < 0.001
How much distress does it cause you when your child is crying? (5-point Likert scale: *values 4–5*)	*n* = 501 3.59 (1.22)	*n* = 91 4.05 (0.95)	z = –3.208; *p* = 0.001
Medical diagnoses: Loss of appetite – normal weight gain			
Is feeding your child a challenge for you? (5-point Likert scale: *values 4–5*)	*n* = 534 1.72 (1.03)	*n* = 28 2.39 (1.47)	z = –2.38; *p* = 0.018
Medical diagnoses: No weight gain or weight loss – alimentary			
Is feeding your child a challenge for you? (5- point Likert scale: *values 4–5*)	*n* = 534 1.72 (1.03)	*n* = 28 2.39 (1.47)	z = –3.71; *p* < 0.001
Medical diagnoses: Sleep disorders (sleep awakenings, sleep-onset problems)			
Generally, how many times does your child wake up during the night? (*4 times or more*)	*n* = 543; 1.71 (1.04)	*n* = 19; 2.79 (1.40)	z = –6.618; *p* < 0.001
How much distress does it cause you when your child wakes up? (5- point Likert scale: *values 4–5*)	*n* = 467; 2.28 (1.26)	*n* = 91; 3.48 (1.29)	z = –7.51 *p* < 0.001
How much distress does it cause you to put your child to sleep? (5-point Likert scale: *values 4–5*)	*n* = 499; 1.76 (1.00)	*n* = 92; 2.55 (1.32)	z = –5.75; *p* < 0.001

Ethical Approval

The Institutional Ethics Committee of Heim Pál Children's Hospital approved the study (authorization number: 11/04.2010).

Informed Consent

Informed consent was obtained from the parents of all individual participants included in the study.

4. Results

4.1 Regulation Disorders in Medical Examinations and Screening Program

A total of 1133 mothers (Table 5) answered the questionnaires.

Table 5 Demographic variables*

Variable	Sample of mothers who filled in the questionnaires (N = 1133)	Subsample where medical examinations were also conducted (n = 619)
	Percent/Mean (SD)	Percent/Mean (SD)
Child's gender		
Boy	52.7%	55.2%
Girl	47.3%	44.8%
Child's age (months)	15.3 (10.8)	15.02 (11.07)
0-2	9.7%	12.1%
3-5	14.9%	15.9%
6-8	10.1%	8.5%
9-11	10.6%	10.3%
12-17	16.0%	15.4%
18-23	13.2%	12.0%
24-36	25.4%	25.7%
Number of children in the family	1.7 (0.9)	1.7 (0.9)
No siblings	52.7%	52.4%
1 sibling	35.5%	35.8%
≥ 2 siblings	11.8%	11.8%
Oldest	58.3%	57.6%
Second	31.6%	31.6%
Multiple	10.1%	10.8%
Age of Mother (years)	32.0 (5.1)	31.68 (5.26)
≤ 25	10.5%	11.9%
26-30	25.6%	25.1%
31-35	40.0%	40.3%
36-40	20.2%	19.4%
≥ 40	3.7%	3.3%
Married/in common-law marriage	93%	90.7%
Maternal education		
Maximum elementary or skilled worker	17.7%	20.6%
High school	34.9%	34.0%
Postgraduate/College degree or more	47.3%	45.4%
Employed	66.2%	65.2%

*Frequencies for valid answers. The proportion of missing values is 0-5%.

In a subsample, 619 children had also medical examinations. The sex distribution was almost half and half, male and female, in both groups. The children's ages and other sociodemographic factors were almost the same or very similar in each subgroup. In the whole sample, the average age of children was 15.3±10.8 months. The average number of children in the families was 1.7±0.9. The average age of the mothers was 32±5.1 years, and more than 90% were married. In addition to medical diagnoses, the main early childhood behavior regulation disorders are also categorized in **Table 6.**

In the subsample in which medical examinations were conducted, excessive crying and/or restlessness was present in 15.0%, sleep disorders in 15.2%, breastfeeding problems in 10.3%, and collective feeding disorders in 14.8%. The prevalence of constipation was 4.0%, while abdominal colic was present in 12.3%. Medical examinations were followed by a deeper screening program for regulation disorders in 183 cases, while in 436 cases this was not necessary.

Table 5 presents the prevalence of different disease and disorder categories in each subgroup, showing higher prevalence of regulation disorders in the screening subgroup.

Table 6. Frequency of early behavior regulation problems and other frequent medical diagnoses

Diagnostic categories in the medical examinations	Subsample where medical examinations were conducted (*n* = 619)	Not referred to screening program (*n* = 436)	Referred to screening program (*n* = 183)
Excessive crying, restlessness	15.0%	5.7%	37.2%
Sleeping problems			
Sleep disorders (sleep awakenings, sleep-onset problems)	15.2%	0.7%	49.7%
Snoring	2.9%	1.6%	6.0%
Feeding and weight gain problems			
Breastfeeding difficulty	10.3%	4.1%	25.1%
Loss of appetite – normal weight gain	5.0%	1.8%	12.6%
No weight gain or weight loss – alimentary	3.2%	0.9%	8.7%
No weight gain or weight loss – organic	6.6%	8.3%	2.7%
Breathing problems			
Irregular breathing	4.5%	4.8%	3.8%
Affective apnea	1.9%	1.6%	2.7%
Breathing stops	6.6%	9.2%	0.5%
Indeterminate symptoms of the infant	10.5%	12.8%	4.9%
Symptoms of possible neurological conditions			
Uncertain sickness, bizarre movements	4.8%	5.5%	3.3%
Activity or concentration difficulties	4.4%	1.4%	11.5%
Pulmonological conditions or recurrent upper airway infections			
Recurrent upper airway infections	24.2%	25.5%	21.3%
Recurrent wheezing	23.9%	30.7%	7.7%
Subglottic laryngitis	9.9%	11.5%	6.0%
Gastrointestinal complaints			
Abdominal colic	12.3%	8.7%	20.8%
Constipation	4.0%	1.6%	9.8%

* In n=619 cases, medical examinations were carried out, followed by a deeper screening program for regulation disorders in n=183 cases, while in n=436 cases this was not necessary.

Comorbidity Between Different Early Childhood Regulation Disorders

In cases in which excessive crying was present, the comorbidity with sleep disorders was 50% ($\chi^2(1)=106.20$; $P<0.001$); with breastfeeding disorders 22.6% ($\chi^2(1)=17.69$; $P<0.001$); and with loss of appetite 11.8% ($\chi^2(1)=10.70$; $P<0.001$). In those cases in which sleep disorders were present, the comorbidity with breastfeeding disorders was 39.1% ($\chi^2(1)=31.60$; $P<0.001$). Other data are displayed in **Table 7**.

Table 7. Comorbidity between different early childhood regulation problems*.

COMORBIDITY Diagnostic categories in the medical examinations	Excessive crying, restlessness		Sleep disorders (sleep awakenings, sleep-onset problems)		Breastfeeding difficulty	
	No vs. Yes %	Crosstabs (χ^2-tests)	No vs. Yes %	Crosstabs (χ^2-tests)	No vs. Yes %	Crosstabs (χ^2-tests)
Sleep disorders (sleep awakenings, sleep-onset problems)	8.8% < 50.0%	$\chi^2(1) = 106.20$; $p < 0.001$				
Breastfeeding difficulty	8.2% < 22.6%	$\chi^2(1) = 17.69$; $p < 0.001$	12.4% < 39.1%	$\chi^2(1) = 31.60$; $p < 0.001$		
Loss of appetite – normal weight gain	3.8% < 11.8%	$\chi^2(1) = 10.70$; $p = 0.001$			4.0% < 14.1%	$\chi^2(1) = 12.30$; $p < 0.001$
No weight gain or weight loss – alimentary					2.3% < 10.9%	$\chi^2(1) = 13.56$; $p < 0.001$

*Crosstabs (χ^2-tests): χ^2(df); p; frequencies of joint regulation disorders. The prevalence of important regulation disorders in subgroups where a specific disorder is present or not. E.g. If excessive crying is present, sleep disorders are also present in 50% of the cases, but this proportion is only 8.8% in a subgroup where excessive crying is not a significant complaint.

Comorbidity Between Early Childhood Regulation Disorders and Other Health Conditions

In those cases in which excessive crying was present, the comorbidity with concentration difficulties was 10.8% ($\chi^2(1)=10.71$; $P<0.001$) and with abdominal colic it was 26.9% ($\chi^2(1)=21.67$; $P=0.001$). When sleep disorders or breastfeeding difficulties or organic feeding difficulties were diagnosed, abdominal colic was also present in 21.3%

($\chi^2(1)=8.33$; $P<0.001$), 23.4% ($\chi^2(1)=8.25$; $P=0.004$), and 34.1% ($\chi^2(1)=19.50$; $P<0.001$) of the cases, respectively. Interestingly, pulmonological conditions or recurrent upper airway infections were more frequent in the subgroups in which regulation problems were not a concern. The other relationships are shown in **Table 8**.

Table 8. Comorbidity between early childhood regulation problems and other health conditions*.

COMORBIDITY Diagnostic categories in the medical examinations		Activity or concentration difficulties %	Recurrent upper airway infections %	Recurrent wheezing %	Subglottic laryngitis %	Abdominal colic %	Cons-tipation %
Excessive crying, restlessness	… not present vs. present	3.2 < 10.8	26.0 > 14.0	27.2 > 5.4	11.0 > 3.2	9.7 < 26.9	
	Crosstabs (χ^2-tests)	$\chi^2(1) = 10.7$; p = 0.001	$\chi^2(1) = 6.27$; p = 0.012	$\chi^2(1) = 20.66$; p < 0.001	$\chi^2(1) = 5.41$; p = 0.020	$\chi^2(1) = 21.67$; p < 0.001	
Sleep disorders (sleep awakenings, sleep-onset problems)	… not present vs. present	3.4 < 9.6		27.4 > 4.3	11.2 > 2.1	10.7 < 21.3	3.2 < 8.5
	Crosstabs (χ^2-tests)	$\chi^2(1) = 7.22$; p = 0.007		$\chi^2(1) = 25.53$; p < 0.001	$\chi^2(1) = 7.45$; p = 0.006	$\chi^2(1) = 8.33$; p = 0.004	$\chi^2(1) = 5.72$; p = 0.017
Breast-feeding difficulty	… not present vs. present	3.6 < 10.9		25.9 > 6.3		11.0 < 23.4	
	Crosstabs (χ^2-tests)	$\chi^2(1) = 7.40$; p = 0.007		$\chi^2(1) = 12.24$; p < 0.001		$\chi^2(1) = 8.25$; p = 0.004	
Loss of appetite – normal weight gain	… not present vs. present		25.0 > 3.2				
	Crosstabs (χ^2-tests)		$\chi^2(1) = 7.67$; p = 0.006				
No weight gain or weight loss – alimentary	… not present vs. present	4.0 < 15.0		24.5 > 5.0			
	Crosstabs (χ^2-tests)	$\chi^2(1) = 5.61$; p = 0.018		$\chi^2(1) = 4.06$; p = 0.044			
No weight gain or weight loss – organic	… not present vs. present			25.1 > 7.3		10.7 < 34.1	
	Crosstabs (χ^2-tests)			$\chi^2(1) = 6.65$; p = 0.010		$\chi^2(1) = 19.50$; p < 0.001	

*Crosstabs (χ^2-tests): χ^2(df); P; frequencies of joint diagnoses. The prevalence of important somatic complaints in subgroups where a specific regulation disorder is present or not. E.g. If excessive crying is present, abdominal colic is also present in 26.9% of the cases, but this proportion is only 9.7% in a subgroup where excessive crying is not a significant complaint.

Regulation Disorders in the Parental Report

According to the questionnaire answers, 14.7% of the mothers' reported low self-confidence when interpreting their infant's signs; it was 22.1% in a subgroup that was referred to the screening program. A total of 15.6% of mothers characterized their children as strong criers (24.4% in a subgroup that was referred to the screening program). A total of 16% of the children had some type of feeding or weight gain disorder (32.6% in the screening subgroup), and 10% awoke 4 or more times during the night (21% in the screening subgroup). The frequency of symptoms of crying, feeding, and sleeping per parent reporting are shown in **Table 9**.

Diagnoses of Regulation Disorders in Medical Examinations and Differences Among Maternal Answers in Questionnaires

According to the z-statistics in Mann-Whitney tests, mothers of children with a diagnosis of excessive crying reported significantly more problematic crying behavior (long prolonged crying in early infancy: $P<0.001$, crying and fussiness in the last 2 weeks: $P=0.001$, soothability: $P<0.001$, parental distress: $P=0.001$) compared with those without this diagnosis.

Mothers of children with a diagnosis of loss of appetite or weight loss reported significantly more problematic feeding behavior (feeding as a challenge: $P<0.001$) compared with mothers of children who did not have this diagnosis.

Children with a diagnosis of sleep disorders had significantly more problematic sleep behavior reported based on the parental questionnaire (nightwakings, sleep onset, parental distress compared with those who did not have this diagnosis; $P<0.001$ for all differences) using Likert scale in the questionnaire. Detailed results are shown in **Table 10**.

Table 9. Frequencies of behavior regulation difficulties and feelings about them reported by mothers in questionnaires.

Questions and emphasized values	Sample of mothers filled in questionnares (*n* = 1133) n%	Subsample where medical examinations were also conducted (*n* = 619)n%	Subsample referred to screening program (n = 183) n%	Subsample not referred to screening program (*n* = 981) n%
How confident are/were you in interpreting your infant's signs? (5-point Likert scale: *values 1–3 for low self-confidence*)	1121 14.7%	595 16.5%	181 22.1%	940 13.3%
CRYING				
How can you characterize your child by strong prolonged crying when he/she was a little baby? (5-point Likert scale: *values 4–5*)	1121 15.6%	599 16.5%	180 24.4%	947 13.9%
According to your observations, how much was your child crying or how fussy was your child in the previous two weeks? (*more than 1 hour*) (*more than 3 hours*)	1112 9.3% 4.5%	576 12.3% 8.6%	177 17.5% 5.6%	935 7.7% 3.7%
How could you soothe him/her when he/she was crying? (5-point Likert scale: *values 1–3 for low self-confidence*)	1118 12.5%	597 15.6%	180 20.0%	938 11.1%
How much distress does it cause you when your child is crying? (5-point Likert scale: *values 4–5*)	1113 54.5%	592 61.2%	176 69.3%	937 51.7%
FEEDING				
Does your child have any feeding or weight gain problems? (*yes*)	1099 16.0%	584 18.2%	175 32.6%	924 12.9%
Is feeding your child a problem for you? (5-point Likert scale: *values 4–5*)	1058 9.6%	562 9.4%	175 20.0%	883 7.5%
SLEEPING				
Generally, how many times does your child wake up during the night? (*4 times or more*)	1105 10.0%	587 11.2%	176 21%	929 7.9%
How much distress does it cause you when your child wakes up? (5-point Likert scale: *values 4–5*)	1033 23.6%	558 23.0%	167 34.7%	866 21.5%
How can your child fall asleep? (*it's difficult even after a long process of putting down*)	1105 8.9%	588 9.0%	177 14.7%	928 7.8%
How much distress does it cause you to put your child to sleep? (5-point Likert scale: *values 4–5*)	1115 9.3%	591 9.0%	178 14.6%	937 8.3%

**n* = valid answers to the question; frequency of emphasized values.The total number of answers (n) to separate questions and the proportions of answers (%) indicating problems.

Table 10. Diagnoses of regulation disorders in medical examinations and differences between maternal answers in questionnaires

Medical diagnoses: Excessive crying, restlessness	Not Diagnosed *n*; Mean (SD)	Diagnosed *n*; Mean (SD)	*z*- statistics in Mann-Whitney tests
How can you characterize your child by strong prolonged crying when he/she was a little baby? (5-point Likert scale: *values 4–5*)	*n* = 507 2.16 (1.10)	*n* = 92 2.90 (1.28)	z = –5.205; *p* < 0.001
According to your observations, how much was your child crying or how fussy was your child in the previous two weeks? (*more than 1 hour*)	*n* = 486 2.83 (1.12)	*n* = 90 3.31 (1.28)	*z* = –3.227; *p* = 0.001
How could you soothe him/her when he/she was crying? (5-point Likert scale: *values 1–3 for low self-confidence*)	*n* = 505 4.32 (0.77)	*n* = 92 3.97 (0.90)	z = –3.641; *p* < 0.001
How much distress does it cause you when your child is crying? (5-point Likert scale: *values 4–5*)	*n* = 501 3.59 (1.22)	*n* = 91 4.05 (0.95)	z = –3.208; *p* = 0.001
Medical diagnoses: Loss of appetite – normal weight gain			
Is feeding your child a challenge for you? (5-point Likert scale: *values 4–5*)	*n* = 534 1.72 (1.03)	*n* = 28 2.39 (1.47)	z = –2.38; *p* = 0.018
Medical diagnoses: No weight gain or weight loss – alimentary			
Is feeding your child a challenge for you? (5- point Likert scale: *values 4–5*)	*n* = 534 1.72 (1.03)	*n* = 28 2.39 (1.47)	z = –3.71; *p* < 0.001
Medical diagnoses: Sleep disorders (sleep awakenings, sleep-onset problems)			
Generally, how many times does your child wake up during the night? (*4 times or more*)	*n* = 543; 1.71 (1.04)	*n* = 19; 2.79 (1.40)	z = –6.618; *p* < 0.001
How much distress does it cause you when your child wakes up? (5- point Likert scale: *values 4–5*)	*n* = 467; 2.28 (1.26)	*n* = 91; 3.48 (1.29)	z = –7.51 *p* < 0.001
How much distress does it cause you to put your child to sleep? (5-point Likert scale: *values 4–5*)	*n* = 499; 1.76 (1.00)	*n* = 92; 2.55 (1.32)	z = –5.75; *p* < 0.001

4.2 Results of Tube feeding.

In the Paediatric tube-feeding: An agenda for care improvement and research publication does not analize data (Hopwood 2020). However, during the treatment of tube feed children, the routine and aspect of IMH documentation in clinical records are collected in the Early Childhood Eating and sleeping Disorders Outpatient Clinic. This data processing is in progress.

Demographic data (Table 11), frequency of early behavior regulation problems (Table 12) of tube fed children.

Table 11. Demographic data of tube fed children

Variable	Tube fed children (n=21)
Child's gender	
Boy	28.6%
Girl	71.4%
Child's age (months)	Average age: 16,17 (months)
0-2	0%
3-5	0%
6-8	0%
9-11	23.8%
12-17	42.9%
18-23	19.0%
24-36	14.3%
Number of children in the family	1.2
No siblings	66.7%
1 sibling	14.3%
³2 siblings	19.0%
Oldest	56,7%
Second	19.0%
Multiple	14.3%

PFD-T group In Early Childhood Eating and Sleeping disorders Outpatient Clinic (01.07.2018-30.09.2021)

Table 12. Frequency of early behavior regulation problems

Diagnostic categories in the medical examinations	Tube fed children (n=21)
Excessive crying, restlessness	19.0%
Sleeping problems	
Sleep disorders (sleep awakenings, sleep-onset problems)	19.0%
Feeding and weight gain problems	
Breastfeeding difficulty	61.9%
Loss of appetite – normal weight gain	0%
No weight gain or weight loss – alimentary	38.1%
No weight gain or weight loss – organic	61.9%.
Gastrointestinal complaints	
Abdominal colic	38.1%
Constipation	9.5%

PFD-T group In Early Childhood Eating and Sleeping disorders Outpatient Clinic (01.07.2018-30.09.2021)

In the Early Childhood Eating and Sleeping Disorders Outpatient Clinic we examined 21 PDF-T cases between 01.07.2018-30.09.2021-, which is not suitable for establishing a statistical conclusion.

However, in the analysis of the cases, we saw remarkable data. The prevalence of boys was 28.6%, while girls accounted for 71.4%. In our previous research data in which a sample of mothers who filled in the questionnaires (N = 1133) boys accounted for 52.7%, whereas the prevalence of girls was 47.3%.

Moreover, the age of young children at the time when the problem arose should be underlined.

Our care did not include 0-2, 3-5 and 6-8 month old infants who need tube feeding. At 9–11 months of age, 23.8%, at 12–17 months of age, 42.9%, at 18–23 months of age, 19.0%, and at 24–36 months of age, 14.3% were cared for in the PDF-T group.

The groups with an experimental and organic background in the diagnostic category of no weight gain or weight loss were compared with the corresponding data from the tub fed children group and the For Healthy Offspring project.

All tub fed children had “no weight gain or weight loss” symptoms, with a total of 100% appearing in this group. Of these, the ratio of cases of alimentary and organic origin was 38.1% / 61.9% = 0.62.

In the For Healthy Offspring project, the Diagnostic categories in the medical examination in the referred to screening program group developed as follows, where the total diagnostic category “no weight gain or weight loss” was 11.4%.

Here, the proportion of infants with no weight gain or weight loss - alimentary and no weight gain or weight loss - organic symptoms was 8.7% / 2.7% = 3.22.

The incidence of breastfeeding difficulty is really pronounced, which was 61.9% in the case of tub fed infants. However, in the group referred to screening program, the problem of breastfeeding was mentioned by parents in 25.1% of the cases.

In the tub fed children group, the incidence of excessive crying, restlessness 19.0%, and sleep disorders (sleep awakenings, sleep-onset problems) was 19.0%.

In our large sample (N = 1133) questionnaire study, 15% of mothers reported intensive crying of the infants, and 10% of infants had sleep disorders.

In our data processing, we did not deal with the treatment of patients, but we present two parental letters on the usefulness of tube feeding.

Mother 1:

As a mother of three children, I learned that there was such a baby who is not interested in eating when our little girl was born, and there was none of the formula she would have liked to eat.

Supplementation did not bring any results. We were taken to the hospital, all our tests showed good results yet I was in a huge shock that we came home with a probe. We received a lot of advice from the special education teacher and I needed to watch for our baby's signs. At 14 months, she started to give signs that she wanted to eat and drink. We had a probe for 4 months, every day we tried puree and glass formula first, then a probe that we used as replacement for the last 2 weeks. Conversations with the psychologist helped me a lot in accepting that this was a transitional state, although many times I didn’t

see the end. There was a lot of despair, crying, anger in me about why this is happening to us. Everything has a reason… I felt better after every conversation. I was looking for moms in this situation on several websites, but unfortunately there weren't any. I regret that I couldn't talk to a mom who was over this and would have given some good advice. I couln't have gotten over it alone without my husband's support and understanding, often hurtful shaking which was necessary I can see now. This also wore him down despite he was the more determined and optimistic. I'm glad he was by our side and persevered in difficult times.

I can't be grateful enough to the doctor that after tube weaning, she kept calming and reassuring us on a daily basis and helped us through this difficult period.

Mother 2:

One child does not eat. That does not exist. That can't be possible, eating is an instinctive thing, you can't survive without it. Everyone knows that. So what if it's not? Until my third child was born, it never occurred to me that a child really doesn't eat. I thought that her mom was overly worried about this and that this was just a little complaint. Now I know it's not. It can be a hell of a nerve-wracking, angry feeling that poisons days, nights, life, family life. My third child is a lovely little girl with down-syndrome. By the age of four months she had already decided not to eat, and that a few sips of breast milk is enough for her... we are over much more, stirrups, leukemia, chemotherapy, heart involvement. I wanted to avoid the gastric tube at all cost, but it saved her life.

Who helps? Doctors say, "Mom, she will eat, because of the disease she did not eat." "All right, she will eat; she should taste what she wants." Many people make you count calories, the scale becomes an enemy, and worry becomes a bad companion.

The family is collapsing spiritually. I thought no one was dealing with a similar situation, it's just us, we're alone on the planet with it. That's when the outpatient clinic appeared before us, where they understood what was wrong, felt with us, took our hands and cared for us. They want to help just as it is good for us. The greatest thing that we get is that we are not alone on this dark, tiring, bumpy road. They turn to us with love, do not let us get discouraged, praise and encourage us, list good examples.

5. Discussion

Parents consult a paediatrician because the child's behaviour is of concern to them and expect treatment, explanation and reassurance. Ascertaining the factors producing the symptoms often requires a multidisciplinary approach (Scheuring 2016). Furthermore, a special awareness is needed to define the symptoms and to communicate effectively with the parents. This is particularly true in disorders of regulation (Mares et al, 2011). The paediatrician may find problems difficult to manage when the symptoms observed in the child are inconsistent with those described by the parent. Feeding problems, for example, rank highly in this group—no clear medical explanation can be found in more than 80% of cases (Cole et al, 2011)—and yet the infant is symptomatic and the parents anxious and concerned. Parents' complaints must be taken seriously because if they think that there is a problem, then there is a problem (Kerzner et al, 2015). Parental anxiety and infant distress can become self-perpetuating. We call this a "misjudged symptom" in the infant and suggest conceptualizing the infant's symptom in the context of parents' complaints and concerns. The symptom is real enough but often not fully explained by a medical cause, thus it may not need actual therapy, only changes in the infant's lifestyle, and reassurance and support for the parents. A functional rather than an organic explanation is assumed and the persistence of the symptoms is understood to result from maladaptive coping in the parent or infant or some difficulty in their relationship (Mares et al, 2011).

Approaching the child's pathological symptoms and/or the parents' complaints from a bio-psycho-social model is effective in recognising, evaluating and treating presentations where parental responses to their symptomatic infant contribute to an infant with persisting distress. Paediatricians benefit from acquiring basic competencies in infant mental health (Briggs et al, 2007), and from working in collaboration with a multidisciplinary team when organic and functional disorders co-occur (Sharp et al, 2017).

Crying is part of the normal development of an infant. It is a form of communication with parents and results from various stimuli, such as hunger, discomfort, or pain. Excessive crying in the early months is a frequent concern. Pediatricians have to understand and adequately manage the problem and offer support to exhausted parents. Excessive crying may interfere with the mother-infant, father-infant, and mother-father interactions and may increase the risk of child abuse (Botha et al, 2019, Tedgård et al, 2020). Over the last 15 years, other regulatory disorders of early childhood have attracted the increased

attention of both researchers and pediatric practitioners (Rocha et al, 2019, Toffol et al, 2019, Northrup and Iverson 2020).

Sleeping Disorders

In international pediatrician surveys and cross-cultural comparisons, sleeping disorders (night awakenings and sleep-onset difficulties) are one of the most frequent (10-76%) parental concerns (Mindell et al, 2010). In our large sample (N=1133) questionnaire study, 10% of the children had sleeping disorders. In a subsample in which diagnoses were determined based on medical examinations and consultations, we found an incidence of 15.2% for sleep disorders. This rate was similar to reports from other countries (Mindell et al, 2010).

Excessive Crying

The occurrence of excessive crying was 8-30% in previous large-sample studies (Wurmser et al, 2001, Kim 2011, Reijneveld et al, 2001). In our questionnaire study, 15% of mothers reported intensive crying in the infants. In a subsample in which diagnoses were determined based on medical examinations and consultations, we found an incidence of 15.0% of excessive crying and/or restlessness. Prevalence rates for excessive crying were lower in some European countries, with 1.5% in the Netherlands (Mindell et al, 2010) and 9.2% in Denmark (Alvarez 2006), but comparable to the 16.3% reported in Germany (Kries et al, 2006).

Eating Disorders

Eating disorders are also common in infancy. Prevalence numbers range from 20% to 25% in the normal population (McDermott et al, 2008, Chatoor 2009, Wright et al, 2007) and from 40% to 80% in infants with disabilities. Mild feeding difficulties occur in approximately 30% of children [4]. The prevalence of clinical feeding disorders is 3-10% (Corbett et al, 2004), and the incidence of more severe failure to thrive is about 3-4% (Thiel-Bonney and Hofacker 2015).

According to our questionnaire results, 16% of the children had feeding disorders. In a subsample in which diagnoses were determined based on medical examinations and

consultations, we found an incidence of 10.3% for breastfeeding disorders and 14.8% for different feeding disorders.

Sleep and feeding disorders are the leading concerns in clinical samples. In a large sample (N=701) in one of the most renowned European clinical programs, the Munich Program (Wurmser and Papousek 2008), occurrence of problems for children were the following: sleep disorders (62.8%), feeding disorders (40.4%), chronic restlessness-motor activity-lack of interest in play (30.1%), excessive crying (29.4%), dysfunctional sleep-wake organization (25.8%), excessive defiance (20.3%), excessive clinging-separation anxiety-social withdrawal (12.3%), and aggression-oppositional behavior (6.8%).

Multiple Regulatory Disorders

Behavioral disorders in infancy can affect an infant's development practitioners (Rocha et al, 2019, Toffol et al, 2019 , Hemmi et al, 2011, Bilgin et al, 2020). Furthermore, infants with behavioral disorders are more likely to have impaired parent-infant relationships relationships (Northrup and Iverson 2020, Papousek and Hofacker 1998, Martini et al, 2017). Approximately 20% of all infants show symptoms of excessive crying, sleeping, or feeding disorders in the first year of life (Hemmi et al, 2011). The prevalence of colic in infants is about 20%, but it depends on parental perception of crying (Bellù and Condò 2018). In our study, the prevalence was 12.3%. In a systematic review and meta-analysis, colic prevalence at 5-6 weeks of age (25.1%) was significantly higher than colic prevalence at 8-9 weeks of age (10.8%) (Wolke, Bilgin 2017). Most maternal and child health nurses were unaware of the evidence that crying is not associated with gastro-esophageal reflux, but most of them reported that reflux causes pain (McGann et al, 2017).

Further, a small minority of children (1-2%) will manifest all 3, leading to multiple regulatory disorders (Kries , Kalies , Papousek 2006) (Schmid , Schreier , Meyer 2010). Infants with multiple moderate-to-severe regulatory problems experience >10 times the odds of clinically significant mental health concerns during childhood, and these symptoms appear to worsen over time (Cook et al, 2019).

Comorbidity

Little is known about the association between excessive crying and sleeping or eating disorders in population samples (Barr 1998). We found comorbidity among different regulation disorders. Where one type of behavior regulation disorder was present, another type of regulation disorder was more frequently diagnosed (**Table 7**). Crosstabs (c2 tests) have proved ($P<0.05$) that infants who were referred to the screening program because of medical considerations had more frequent behavior regulation disorders than other infants in our study. This, in turn, indicates that the differential diagnostic process was successful in our program.

Wolke et al (Wolke et al, 1995) found that 32.7% of parents reported that their infant had a crying, sleeping, or feeding disorder, and a further 14.6% reported their infant as having more than one of these disorders. Specifically, comorbidity was most likely to occur between crying and sleep disorders. Multiple regulatory problems may identify infants with a high burden of comorbidity that extends into childhood (Cook et al, 2019, Olsen et al, 2019).

In a retrospective study by von Kries et al (Kries et al, 2006), a higher prevalence of sleep and eating disorders was found in children up to 4 years of age who were reported to have had excessive crying beyond the sixth month. In our study, the connection between sleep disorders and excessive crying was 50%, but some studies have not found a relationship between excessive crying and sleep disorders and other indicators of multiple regulatory disorders (. Kirjavainen et al, 2001), while other studies have found either sleeping or other regulatory disorders (Wolke et al, 1995, Canivet et al, 2000). The few children with excessive crying and either severe sleeping or eating disorders might constitute a group of infants with multiple regulatory disorders outside the continuous spectrum of normal behavior Barr 1998).

Moreover, there is growing evidence of the negative implications for infants whose excessive, persistent crying is present with other regulatory disorders, such as feeding and sleeping disorders (Wolke et al, 1995, Wolke et al, 2009).

A meta-analysis of 22 longitudinal studies showed evidence associating excessive crying and other regulatory disorders (sleeping and eating) in the first months of life with adaptive problems at school age, mainly related to attention deficit-hyperactivity disorder symptoms and associated behaviors (Hemmi et al, 2011, Bilgin et al, 2020, Schmid et al,

2014, Santos et al, 2015). In our study, the comorbidity between excessive crying and concentration difficulties was 10.8%.

There was no connection between regulation and breathing disorders. Breathing stops and sleep disorders were successfully differentiated. Among those diagnosed with sleep disorders, there were fewer infants who had breathing stops than among the others. Also, there was no relationship with symptoms of possible neurological conditions and uncertain sickness or abnormal movements.

Infants who had early activity or concentration disorders were significantly more highly represented among those who had behavior regulation disorders as well. The occurrence of abdominal colic and constipation, symptoms that are often found to have a psychosomatic background, also correlated with the occurrence of other regulation disorders. The occurrence of diagnoses of excessive crying, sleep disorders, and breastfeeding and other feeding disorders was significantly lower in children in whom recurrent upper airway infections, recurrent wheezing, or laryngitis were diagnosed (**Table 7**).

Questions about both parental observations and subjective feelings were asked in questionnaires. Some important extreme values of questions are presented for the whole sample, for the subsample in which medical examinations were also conducted, and for the subsample that was referred to the screening program. Mothers of infants who were referred to the screening program because of medical considerations reported more problems in the questionnaires than other mothers in our study (**Table 8**).

The mothers of the infants with diagnoses of excessive crying, sleep, or feeding disorders reported significantly more problematic behavior in questionnaires as well (**Table 3**).

Our screening program included children who showed signs of regulation disorders and who were referred for a detailed diagnostic evaluation. The incidence of diagnoses in this program was the following: sleep disorders (49.7%), excessive crying (37.2%), and functional feeding disorders (no organic background; 21.3%).

In order to offer appropriate medical support, the differential diagnostic process is important in separating acute secondary symptoms (e.g., crying, mild and transient sleep and feeding disorders because of general discomfort, nonspecific complaints, pain) of frequent child illnesses (eg, respiratory diseases) from comorbid chronic behavior regulation disorders. In our study, we investigated the relationship between regulation

disorders and other health conditions from medical records for which a screening model enabled careful and thorough differential diagnostics.

Outpatient treatment is sufficient for crying or sleeping disorders in infancy. However, hospitalization may be required for feeding disorders because not all feeding disorders can be treated on an outpatient basis (Bolten 2013).

In a study conducted by Schmid and Wolke (Schmid and Wolke 2014), excessive infant crying (10.1%) was specifically associated with maternal anxiety disorders, especially in infants of younger and less educated first-time mothers. Feeding disorders (36.4%) were predicted by maternal anxiety (and comorbid depressive) disorders in primiparous mothers and infants with lower birth weight. Infant sleeping disorders (12.2%) were related to maternal depressive (and comorbid anxiety) disorders irrespective of maternal parity (Petzoldt et al, 2016, Samdan et al, 2020, Dias et al, 2020, Væver et al, 2020).

In our experience, designating risk groups in pediatric care is a complex problem. On the one hand, many parents may report regulation disorders, while based on a strict diagnostic system, a clinical disorder cannot be determined. On the other hand, we can assume that there are many hidden cases in which infants could have a clinically relevant regulation disorder but their parents do not interpret these behaviors as being problematic and do not report them to pediatricians or health care nurses. Thus, we can assume that some cases could remain hidden, while in others, study is requested without a clinical basis. In the latter circumstance attention from a therapeutic perspective is still necessary because of the parents' concern. Questions about the parents' feelings about the specific problems can contribute to a better understanding of the actual situation.

The Paediatric tube-feeding

An agenda for care improvement and research publication does not favour particular clinical practices or research methods. We suggest that three principles should underpin the priorities listed above. Heeding calls in recent research, these fall under a family-centred guiding ethos of involvement, respect and connection.

We therefore advocate care improvement and research that happens through and produces new connections between clinicians, families and each other. That is a major aspect for

continue the research in the Early Childhood Eating and sleeping Outpatient Clinic during our multidisciplinary work (Martonosi et al, 2018, Gulácsi et al, 2017).

Limitations

Most of the data in the current study were collected via maternal reports. These are often limited by social desirability and reporter bias. Another limitation of this study was our lack of access to father-child interactions. Thus, future research should include both mothers and fathers. Another limitation there was no ethnic diversity, with only white participants in the study. It is important to note that our study used only a short period of data collection. Finally, our sample is not representative; the results can be regarded as estimations for recognizing early childhood regulation disorders in pediatric care.

6. Conclusions

The For Healthy Offspring Project was the first study to examine the prevalence and the complex (medical and psychosocial) background of the classic behavior regulation disorders (excessive crying, feeding, and sleep problems) in infancy and toddlerhood in Hungary. In this article, the relationship between regulation disorders and other health conditions were investigated. Crying and sleep and feeding disorders are challenging for most parents, but only a small fraction of these cases can be categorized as clinical disorders. Although our study is not representative, according to our findings, we can hypothesize that the general incidence of early childhood regulation disorders in international research of 5-15% is likely similar to that found in Hungary as well. This study added more information about the associations between regulation problems and other health conditions. Our model for screening enabled the careful differential diagnostic process of separating acute secondary symptoms from comorbid chronic behavior regulation disorders. We highlighted that no other data are currently available on the frequency and types of early childhood regulation problems in Hungary. In order to effectively recognize early behavior regulation disorders in daily practice, diagnostic instruments widely used in international field should be adapted in general Hungarian pediatric care.

Children who tube feed deserve the best possible care to reduce the severity, frequency, and duration of tube feeding as well as any adverse effects. This agenda aims to ensure children who tube feed thrive, and enjoy mealtimes plus all the benefits of interacting with siblings and friends as members of families whose wellbeing is intact. The agenda is a call for specific priorities in research and care improvement, grounded in the principles of involvement, respect and connectedness.

It is pivotal to advocate infant mental health in terms of assessment, prevention, and intervention. In particular, there is a great deal of responsibility for pediatricians who are among the first to encounter the problem, especially in the case of serious sickness. Recognizing and managing children’s signs requires infant mental health knowledge, which is a subspecialty within a number of different disciplines, such as pediatrics.

It is recommended to pay attention to the problems and signs of the infant and the toddler as soon as they appear, to evaluate the complaint properly, to provide the families with expert advice and, if necessary, to follow the clinical manifestation of the disorder. Effective care can be achieved through the active involvement of parents, their education,

and the collaboration of fellow professionals working with young children through multidisciplinary team work. The experience gained during practical work and the collection of clinical data provide a wide range of opportunities for professional collaboration in research and practice.

7. Summary

Emotion and behavior regulation disorders in infancy and toddlerhood are quite frequent, with an prevalence of 5-20%. The bio-psycho-social model constitutes a useful theory for understanding and treating regulatory disorders affecting the healthy development of infants and young children as it is a comprehensive framework emphasizing not only biological causes, but also psychological factors and social effects.

The For Healthy Offspring Project (n=1855) is the first Hungarian study developing an effective model for screening and examining the prevalence and complex (medical and psychosocial) background of classic behavior regulation disorders such as excessive crying, feeding, and sleep problems in infancy.

Our hypothesis was that the prevalence of regulation disorders in Hungary is similar to that of other countries; moreover, excessive crying, sleep, and feeding disorders are strongly related, and that these regulation problems may also be associated with other diseases.

During our research the assessment and management of tube fed children (n=21) had been integrated into the interdisciplinary medical care of the newly set up Early Childhood Eating and Sleeping Disorders Outpatient Clinic.

Our Healthy Offspring Project investigates the cumulative combination of somatic, interactional, and psychosocial environmental risk factors affecting early childhood development, whereby we have developed a complex model to screen for regulatory problems in early childhood. Further, we report the prevalence of major regulation disorders (excessive crying, sleep and feeding problems) in our sample, and the associations between regulation disorders and other examined medical conditions. Additionally, we present data with regard to early behavior regulation problems collected from tube fed children during their treatment in our Early Childhood Eating and Sleeping Outpatient Clinic.

The experience gained during practical work and the collection of clinical data provides a wide range of opportunities for collaboration between clinical practice and research.

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