



DOCTORATE PROGRAM IN PSYCHOTHERAPY

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Video Feedback Intervention to Enhance Parental Reflective Function in Primary Caregivers of Children with Severe Psychiatric Disorders. Feasibility Randomized Trial

by

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1. Abstract

Parenting interventions for children who are admitted in a psychiatric hospitalization are scarce, Video Feedback (VF) intervention have proved to be effective in promoting parental and child wellbeing. Parental Reflective Functioning (PRF) is one of the parental abilities that can be improved with VF and could be especially important in coping with conflict and negative emotions in older children. The objective of this research was to evaluate the feasibility and acceptability of implementing Video Intervention Therapy (VIT) to improve RPF of primary caregivers of children hospitalized in a psychiatric service and provide evidence for a larger randomized control trial.

The study was a single center, two-arm feasibility randomized control trial with a qualitative component. Block randomization was done to generate a 2:1 allocation, leaving more participants in the intervention group. The intervention comprises four modules; every module has a one video-recorded play session and one VIT session (in a group setting) per week. Evaluation of caregivers included assessments of PRF and wellbeing, while child assessment included parent-ratings and clinician-ratings of symptomatology and general functioning.

Thirty participants were randomized; eligibility and recruitment rate were 70.6% and 83.3% respectively. Compliance-to-intervention rate was 85% in the VIT group and 90% in the control group. The intervention was acceptable to participants and feasible for therapists to deliver. Outcome data should be treated with caution due to the small numbers involved yet indicate that the VIT may have a positive effect in improving parental and child mental health.

In conclusion, VIT was feasible to deliver and acceptable for participants, therapist and the staff unit involved, there being sufficient evidence to undertake, with some design modifications, a full-scale effectiveness RCT. High quality preliminary evidence would indicate that VIT, as a tailored, evidence-base intervention, is feasible to implement in child psychiatric public services.

2. Introduction

School-aged children in need of inpatient psychiatry care present a challenge for public health. Children often belong to “multi-problem” family systems with psychiatric pathologies in other members of the family and various psychosocial problems including poverty, neglect, violence among others (Bodden & Deković, 2016; Oliveira et al., 2014). Limited and scarce resources make it difficult to respond to the wide variety of problems that patients and their families bring to the hospital unit with evidence-based interventions. It is insufficient to focus on the child's individual factors (psychiatric, neurological or other) to understand and address their mental health difficulties (Rimehaug, 2019). Even though child psychiatric hospitalization is rather infrequent, in countries with extensively developed community and public mental health, the need for pediatric psychiatric beds has increased in recent decades and is associated with a rise in the presentation of severe behavioral problems and greater use of psychotropics (Blader, 2011; Flora De La & Ricardo, 2009a; Holtmann et al., 2010; James et al., 2010; Van Horne et al., 2015). A psychiatric hospitalization, in addition to being an expensive intervention, could lead to deleterious consequences in the child's psyche. It has been observed that hospitalized children might experience feelings of distress, abandonment, and guilt (Hernández Pérez & Rabadán Rubio, 2013). Although reviews on the subject conclude that the net effect of hospitalization may be beneficial (Hayes et al., 2018).

There are a variety of standardized family interventions for outpatient treatment of children and their families with mental health problems (Sharma & Sargent, 2015), but there is a lack of evidence regarding brief, effective, and feasible family interventions to perform in the context of a psychiatric hospitalization (Schwenck et al., 2016). Most family interventions are highly specialized, long-term and not suitable for implementing in a short period of time (Pedersen et al., 2019; Sharma & Sargent, 2015). Nevertheless, Video-Feedback (VF) interventions, as a group, is novel, attachment-based intervention with a robust body of evidence showing its potential to promote positive parenting in fewer sessions. To date, there are three meta-analyses which conclude that this type of interventions are useful to improve parental sensitivity, attachment security and interaction (Bakermans-Kranenburg et al., 2003; Fukkink, 2008; O'Hara et al., 2019), however, the majority of the primary studies focus on dyads of children under 5 years of age. Nevertheless, attachment-based interventions could be

use also with parents of school age children, adolescence and adult couples (H. Steele & Steele, 2018).

Attachment theory emerged with Bowlby in 1969 (Bowlby, 1976, 1983). He theorized that infants have a biological urge to form attachments, and these interactions with their primary caregiver and the resultant bonding create an environment of safety for the infant. Later Mary Ainsworth showed that the behavior of a safe infant is due to a caregiver's sensitive and attuned interactions (Bretherton, 1992), but maternal sensitivity wasn't sufficient to explain intergenerational transmission of secure attachment (De Wolff & Van Ijzendoorn, 1997). Another trait emerges to fill this transmission gap, the parental mentalization or reflective function (Fonagy & Target, 2005). Mentalization is defined as the capacity to understand and interpret one's own behavior and those of others as an expression of mental states, such as feelings, thoughts, fantasies, beliefs and desires and is fundamental to emotional regulation (Fonagy et al., 2004). Reflective function (RF) is the operational definition of mentalization. RF is a scale made to measure mentalization in the context of an Adult Attachment Interview and it is highly correlated to child's attachment at 12 months (Fonagy et al., 1991, 1998; Sharp & Fonagy, 2008; Slade, 2005). A recent meta-analysis found that Parental Mentalizing or Parental Reflective Functioning (PRF) is a better predictor of secure attachment than parental sensitivity (Zeegers et al., 2017). In addition, PRF is fundamental for the development of children's mentalization skills, which normally fully develop between 7 and 12 years of age (Midgley et al., 2017). Although empirical data on the relationship between PRF of school children and adolescents are limited, a positive correlation has been found between PRF with preadolescent and adolescent mentalization and social adjustment (Benbassat & Priel, 2012; Ise et al., 2015; Rosso et al., 2015). Parental ability to understand the child's mental states could be an important protective factor against the development of psychopathological conditions or health-risk behaviors (Midgley et al., 2017; Rosso et al., 2015).

In terms of inpatient childcare, enhancing the skills of parents when minding their children with mental health problems could, potentially, improve outcomes and prevent future hospitalizations. Children with psychopathology require their parents and/or caregivers to be highly capable of self-regulation and hetero regulation towards the child. Children with severe mental health problems often have overwhelming internal states and express this through

risky, aggressive or peculiar behavior (Midgley et al., 2017). An adequate FRP allows caregivers to understand the child's maladaptive behavior in relation to these disturbed mental states, supporting the emotional regulation of the adult in the interaction with the child, and the inclusion of a broader perspective to interpret the child's behavior and the emotional hetero regulation that is necessary in times of crisis.

In order to develop an attachment-based intervention to increase PRF in caregivers of hospitalized children in a public child psychiatry unit, a feasibility study with Video Intervention Therapy (VIT) was designed and implemented in a child psychiatric hospitalization unit in Valparaíso, Chile. This pilot study followed the rationale of clinical trials, since no other published studies were found regarding dyadic interventions in hospitalized children with severe mental health problems, and it was expected that this study would provide the necessary evidence to plan a larger scale trial to evaluate the effectiveness of the intervention (Eldridge, Chan, Campbell, Bond, Hopewell, Thabane, Lancaster, O'Cathain, et al., 2016).

The development of this doctoral dissertation comprises three articles. All of them published in open access journal for better dissemination. The third article is actually under review.

1. “A cross-sectional study on the characteristics and factors associated with the clinical course of child and adolescent patients hospitalized in a public child and adolescent psychiatric unit of Chile”. This article provided information on the target population for whom the intervention was later designed.
2. “Video feedback intervention to enhance parental reflective functioning in primary caregivers of inpatient psychiatric children: protocol for a randomized feasibility trial”. This article is a useful step in the design and implementation of clinical trials, since it explicitly describes the rational of the research design and avoids publication biases.
3. “Video Intervention Therapy for Primary Caregivers in a Child Psychiatry Unit: A Randomized Feasibility Trial”. The last article presents the results of the study and responds to the objectives of the proposed research.

The work of this research was developed over a period of four years, during which an initial evaluation of this tailored intervention was designed, implemented and carried out. Reading

the results, including participants' voices, it is possible to appreciate the potential of this brief intervention to provide support and specialized assistance to adults who are the attachment figures for hospitalized children. This study constitutes the first steppingstone for the development of a long-term line of research with parents and caregivers of children with severe mental health problems. This is undoubtedly a challenging task, which will require scientific and clinical rigor to provide public care services and their users a culturally sensitive and evidence-based therapeutic alternative.

3. Objectives

General objectives

1. To assess the feasibility and acceptability of perform a future Randomized Control Trial (RCT) with a psychotherapeutic intervention using Video Intervention Therapy (VIT) to improve the Parental Reflective Function (PRF) in primary caregivers of children and early adolescents hospitalized in a psychiatric ward.
2. To provide data to estimate the parameters required to design a definitive RCT with a psychotherapeutic intervention using VIT in primary caregivers of children and early adolescents hospitalized in a psychiatric ward.

Specific objectives

For answering the main general objective:

1. Estimate the proportion of the quantity of performed sessions against the quantity of planned VIT sessions.
2. Estimate the proportion of participants that complete the entry evaluation.
3. Estimate the proportion of participants that complete previous evaluations and at the end of the intervention
4. Estimate the proportion of participants that complete the 3-months follow-up assessment from the beginning of the intervention
5. Assess the need of introducing changes in the design of a definitive RCT based on the VIT intervention performed (eligibility criteria, at randomization moment, intervention protocol, other)

6. Explore satisfaction and related factors from the caregiver's perspective that participate in the VIT intervention
7. Explore the assessment performed by the hospitalization crew members that accept and participate in the intervention (psychiatrist, nurse and psychologist).

For answering the second general objective:

1. Assess the proportion of hospitalization tutors meeting the eligibility criteria (eligibility rate)
2. Assess the proportion of caregivers that accept the invitation to participate in the study (recruiting rate)
3. Estimate the compliance-to-intervention rate (proportion of caregivers that complete the intervention against the quantity of randomized)
4. Measure key outcome domains (for completion rates, missing data, estimates, variances and 95% confidence intervals for the difference between the intervention and control group).
5. Determine the size of the change effect in the Parental Reflective Function in the group of primary caregivers that participate in a VF psychotherapeutic intervention with respect to a control group

4. Articles

First Article:

A cross-sectional study on the characteristics and factors associated with the clinical course of child and adolescent patients hospitalized in a public child and adolescent psychiatric unit in Chile

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Abstract

Introduction: Patients of the Short-stay Child and Adolescent Unit of the Del Salvador Psychiatric Hospital (Valparaíso, Chile) exhibit different clinical and social characteristics compared to literature reports of other national centers, although published data are scarce.

Objectives: To describe the operation of the Unit, the socio-familial and clinical characteristics of its patients and analyze factors associated with their clinical evolution.

Methods: We performed a cross-sectional study to describe the patients hospitalized over a three-year period. Variables were registered in an anonymized database. Clinical evolution was evaluated over the year following hospital discharge. **Results:** The Unit's model of care can be described as involving biomedical, psychodynamic, and ecological components. We included 98 patients, of which 70.4% were male, and the average age was 11.5 ± 2.3 years. 82.6% were of low socioeconomic status, and 35.7% did not attend school; 98.9% presented family dysfunction, and 91.8% of parents had a history of psychopathology. The most frequent reason for admission was the risk of harm to self or others. The most frequent discharge diagnoses were behavioral, depressive, and personality development disorders. The average length of stay was 41.8 ± 31.1 days. The most commonly used pharmacological agents were antipsychotics and mood stabilizers. Regarding clinical evolution in the first-year post-discharge, 47% were evaluated as positive, 27% regular, and 26% unsatisfactory. The factor associated with an unsatisfactory clinical course was having had in-patient antidepressants. Re-admission during the first-year post-discharge was associated with comorbid substance use disorder. Treatment noncompliance was associated with a history of behavioral disorder at

hospital discharge and having parents with a history of suicide or consummated suicide.

Conclusions: The patient profile is one of low socioeconomic status, severe psychopathology, maladaptive behavior, family dysfunction, and parental psychopathology. Substance use disorder is also associated with readmission.

Main messages

- Research on child and adolescent psychiatric hospitalization is scarce internationally, and a majority of existing work is not recent. In Chile there are only three publications, only one of which represents the public health system that covers 74% of the population.
- Short-stay Child and Adolescent Unit of the Del Salvador Psychiatric Hospital (Valparaíso, Chile) functions by integrating biomedical, psychodynamic and ecological care models.
- Limitations of the present work include potential biases due to heterogeneity in diagnoses given retrospective data collection; unavailability of follow-up data for patients receiving outpatient care at other centers post-discharge; and small sample sizes for association analyses that may have resulted in inadequate power to detect plausible associations.

Introduction

In-hospital treatment is an important aspect in the care and management of children with severe psychiatric disorders, evidenced by the recent increase in the annual rate of psychiatric hospitalizations in children and adolescents in developed countries (Van Horne et al., 2015). This process is costly and not without complications (Green et al., 2007; Scott et al., 2001). In any hospitalization, whether for psychiatric reasons or otherwise, up to 37% of youth may present some psychological sequelae, given the highly stressful situation for the child and family (Vessey, 2003). Further, hospitalization may even have traumatic consequences (Hernández Pérez & Rabadán Rubio, 2013; Méndez et al., 2004).

During their time in hospital, children often suffer feelings of abandonment, and experience loneliness and guilt (Hernández Pérez & Rabadán Rubio, 2013). Regarding hospitalization for

psychosocial reasons, such as suspected maltreatment and/or sexual abuse, the child's understanding of the problem is even more complex (Bella & Borgiattino, 2016). Admission to these units is therefore reserved for patients with severe psychiatric symptoms and are associated with complex psychosocial contexts (precarious support network, unprotected environments and/or severe maltreatment) (Costello et al., 1991; Flora De La & Ricardo, 2009b). Thus, hospitalization should only occur where there is capacity to provide clinical stabilization and rapidly achieve a reduction in symptoms and risks (Lamb, 2009).

Although there has been a significant increase in the availability of hospital beds for child psychiatry in Chile since the Ministry of Health implemented their Mental Health Plan in 2000 (Ministerio de Salud de Chile, 2017), there is a significant lack of in-hospital resources for this population, and the appropriate care model is currently under discussion (Sociedad de Psiquiatría y Neurología de la Infancia y Adolescencia (SOPNIA), 2019). Until 2007, there were seven beds exclusively destined for the hospitalization of children and adolescents in psychiatric care in Chile (Pesce, 2014). In 2014, ten short-stay units provided 125 beds, but there was an estimated shortage of at least 20 units (Ministerio de Salud de Chile, 2017). Currently, there are 185 beds for children and adolescents requiring psychiatric care, 42% of which are in the Metropolitan Region and 21% in psychiatric hospitals (Ministerio de Salud de Chile, 2018).

Child and adolescent psychiatric hospitalization units and their therapeutic effectiveness have been described in many international studies (Green et al., 2007). However, results are limited primarily by the lack of standardized measures and difficulties inherent in performing randomized clinical trials in vulnerable populations (Flora De La & Ricardo, 2009a). In Latin America, studies on the subject are scarce. In Chile, characteristics of hospitalized populations and models of functioning have been described mainly for units that are not part of the public health network, that serves 74% of the population (Minoletti & Zaccaria, 2005). Internationally, research in this area is likewise scarce, and existing work is not recent. Adult psychiatric hospitalization in Chile has been extensively reported on, but to our knowledge, there are just three reports involving children and adolescents (Flora De La & Ricardo, 2009b; Pacheco et al., 2007, 2010), two at the same unit (Pacheco et al., 2007, 2010). It therefore seems relevant to address this gap, especially in a public health and regional context.

The Short-stay Child and Adolescent Unit of the Del Salvador Psychiatric Hospital, Valparaíso, Chile, designed for children and adolescents under 15 years of age, commenced operations in 2014 and has eight beds (Díaz, 2014). This article presents the sociodemographic, family, and clinical profile of patients at the Unit. Factors associated with clinical evolution are also analyzed.

Methods

Design and participants

A cross-sectional study was conducted to describe patients hospitalized at the Short-stay Child and Adolescent Unit of the Del Salvador Psychiatric Hospital, from December 2014 to December 2017. Sampling was thus non-probabilistic. For patients who were hospitalized on more than one occasion, the first hospitalization was considered.

Data collection

This study was evaluated and approved by the Research Ethics Committee of the Valparaíso-San Antonio Health Service (approval number 051 2017). De-identified clinical and sociodemographic data were extracted from an anonymized database recorded by the clinical team. Informed consent was requested from the parents to assess and extract data from the clinical record over the course of care. No interviews or direct assessment of the participants were carried out for the purpose of the present study.

Eligibility criteria correspond to those for admission to the Unit: Patients aged 15 years or less, with severe psychiatric pathology that, according to the criteria of the psychiatrist in charge, require hospitalization for diagnosis, psychosocial management and/or treatment. In addition, it was a requirement that patients exhibited stability from a medical-organic point of view. Patients that have violated the law are not admitted to the Unit as they have a separate specialized network for care.

Clinical features were evaluated according to the diagnostic criteria of the Diagnostic and Statistical Manual of Mental Disorders in its Fifth Version (DSM-5) (American Psychiatric Association, 2013). The French Classification of Mental Disorders of Children and

Adolescents (Item early psychosis - invasive developmental disorders) was used to study psychotic disharmony (Beraudi Luppi, 2004).

Clinical records of patients that received outpatient care at the Del Salvador Psychiatric Hospital were reviewed to determine progress at three months, six months and one year following discharge. Progress was categorized as "good," "fair," or "unsatisfactory" according to the criteria used at the Unit. Good clinical evolution is exhibiting a response to treatment during hospitalization, and that response is maintained over the follow-up, exhibiting reduced or ameliorated symptoms that caused their admission. Fair clinical evolution is characterized by a reduction in some symptoms, which overall still affect their functionality, but not enough to require a new hospitalization. Unsatisfactory clinical evolution is exhibited by a relapse of symptoms that motivated hospitalization, such as suicidal behavior, dropping out of school or others requiring readmission.

Data analysis

For descriptive statistics, proportions were used for qualitative variables and means with standard deviations for quantitative variables. Odds ratios with their respective 95% confidence intervals were estimated to analyze factors associated with the clinical evolution. Data were analyzed using the Stata 15 statistical software (Stata Corp, Texas, USA).

Results

The following is a description of the functioning of the Short-stay Child and Adolescent Unit of the Del Salvador Psychiatric Hospital. Then, primary findings are reported according to the sociodemographic, family, and clinical characteristics of the patients, as well as to factors associated with clinical evolution.

Short-stay Child and Adolescent Unit of the Del Salvador Psychiatric Hospital

This unit has a multilevel biopsychosocial model composed of:

1. A biomedical model, led by child and adolescent psychiatrists, occupational therapists and nurses, in charge of diagnosing pathologies and caring for the different needs of patients.

2. A psychodynamic model, led by child psychologists and child and adolescent psychiatrists, associated with the process of psychodiagnosis through projective techniques as well as individual and group interventions. The theoretical perspectives used emphasize Bowlby's attachment theory (Bowlby, 1975) and Winnicott's theory of dyadic relationships and psychic development (Menolascino, 1972).
3. An ecological model developed by Urie Bronfenbrenner (Bronfenbrenner, 1981), which conceptualizes that the subject is a being that influences and is influenced by his or her environment, which is represented by a great interest in generating channels of communication between the different actors involved in the development of the child or adolescent: Coordination with schools, support programs, extended family, and outpatient therapists.

The phases of hospitalization include (Diaz, 2014):

1. Comprehensive diagnosis.
2. Clinical stabilization.
3. Preparation for hospital discharge (pre-release)
4. Follow-up.

Sociodemographic characteristics

Ninety-eight patients were admitted over the study period, 70.4% of whom were men ($n = 69$). Ages ranged between 7 and 16 years, as, exceptionally, a 16-year-old patient with psychological functioning of a child was admitted as hospitalization in the adult units was considered risky. The mean age was 11.5 years (standard deviation of 2.3 years). Children under 10 years of age constituted 23.47% ($n = 23$), 10-12 years old, 36.73% ($n = 36$), and over 12 years old, 39.8% ($n = 39$). A majority (82.6%; $n = 81$) were of a low socioeconomic level, corresponding to groups E and D of the Chilean socioeconomic classification model (Beraudi Luppi, 2004). About a third (35.7%; $n = 35$) were outside of the school system; 22 of these cases were schooled again during hospitalization. Sociodemographic characteristics are presented in **Table 1**.

Family characteristics

Almost all cases ($n = 97$) were classified as belonging to families with dysfunctional environments. The average age of the primary caregiver was 40.1 years (standard deviation of 9.88 years); 28.5% ($n = 28$) of children were institutionalized upon admission and, of these, 46.4% ($n = 13$) did not have a significant caregiver visiting them during hospitalization. 80.6% had a history of some type of serious negligence. 91.8% of parents presented a history of psychiatric pathology, where the most frequent was one of the personality disorders. Family characteristics are summarized in **Table 2**.

Table 1: Sociodemographic characteristics of the participants.

	Total sample (n = 98)	Under 10 years (n = 23)	Between 10 and 12 years (n = 36)	Over 12 years (n = 39)
Age (years)	11.5 (± 2.33)	8.4 (± 0.66)	10.9 (± 1.04)	13.9 (± 0.82)
Male	69 (70.4%)	22 (95.6%)	30 (83.3%)	17 (43.5%)
Low socioeconomic level	81 (82.6%)	19 (82.6%)	30 (83.3%)	31 (79.4%)
Not in school at admission	35 (35.7%)	7 (30.4%)	16 (44.4%)	12 (30.7%)
Falling behind at school	44 (44.8%)	9 (39.1%)	20 (55.5%)	15 (38.4%)

Reasons for admission, diagnosis at admission and discharge

14.2% ($n = 14$) of patients were admitted involuntarily. The most frequent reason for hospitalization was risk of harm to others (61.2%). The distribution changed when stratified by age and/or sex. Regarding the diagnoses at admission, the three most frequent were conduct disorders (56.1%), intellectual disability (27.5%) and major depressive disorder (24.4%). The presence of symptoms from the suicide spectrum was observed in 41.8% ($n = 41$). Psychotic symptoms (either in isolation or in the context of a psychotic syndrome) were observed in

28.5% (n = 28) of cases, while antisocial behaviors were observed in 62.2% (n = 61). The reasons for admission are summarized in **Table 3**.

Table 2: Family characteristics of participants.

		Total sample (n = 98)	Under 10 years (n = 23)	Between 10 and 12 years (n = 36)	Over 12 years (n = 39)
Age of primary caregiver		40.1 (± 9.88)	37.7 (± 8.56)	38.5 (± 10.85)	43 (± 9.05)
Institutionalization of the participant		28 (28.5%)	8 (34.7%)	14 (38.8%)	6 (15.3%)
Lives with biological parents		67 (68.3%)	14 (60.8%)	22 (61.1%)	30 (76.9%)
Family dysfunction		97 (98.9%)	23 (100%)	36 (100%)	39 (100%)
Primary caregiver	At least one parent	74 (75.5%)	17 (73.9%)	27 (75%)	30 (76.9%)
	Without a primary caregiver	13 (13.2%)	4 (17.3%)	5 (13.8%)	4 (10.2%)
	A family member	11 (11.2%)	2 (8.6%)	4 (11.1%)	5 (12.8%)
Parent with psychopathology		90 (91.8%)	20 (86.9%)	34 (94.4%)	36 (92.3%)
Type of parental psychopathology	Personality disorder	60 (61.2%)	17 (73.9%)	19 (52.7%)	24 (61.5%)
	Substance use disorder	43 (43.8%)	9 (39.1%)	22 (61.1%)	12 (30.7%)
	Major depressive disorder	29 (29.5%)	7 (30.4%)	9 (25%)	13 (33.3%)
	Suicidal behaviors	6 (6.12%)	0 (0%)	3 (8.3%)	3 (7.6%)
	Bipolar affective disorder	3 (3.06%)	0 (0%)	1 (2.7%)	2 (5.1%)
	Schizophrenia	2 (2.04%)	0 (0%)	1 (2.7%)	1 (2.5%)
Caregiver unemployed		16 (16.3%)	5 (21.7%)	6 (16.6%)	5 (12.8%)
Presence of gross negligence		79 (80.6%)	20 (86.9%)	30 (83.3%)	29 (74.3%)
Type of gross negligence	Domestic violence	62 (63.2%)	14 (60.8%)	25 (69.4%)	22 (56.4%)
	Case involving prosecution	62 (63.2%)	14 (60.8%)	28 (77.7%)	20 (51.2%)
	Child sexual abuse	19 (19.3%)	6 (26%)	4 (11.1%)	9 (23%)

Table 3: Reasons for hospital admission of participants

Reason for admission	Total sample (n = 98)	Under 10 years (n = 23)	Between 10 and 12 years (n = 36)	Over 12 years (n = 39)
Risk of harm to another	60 (61.2%)	19 (82.6%)	26 (72.2%)	15 (38.4%)
Risk of self-harm	36 (36.7%)	3(13.0%)	8 (22.2%)	25 (64.1%)
Psychomotor agitation	33 (33.6%)	9 (39.1%)	16 (44.4%)	8 (20.5%)
Impossibility of outpatient study and treatment	9 (9.1%)	2 (8.6%)	4 (11.1%)	3 (7.6%)

Values expressed in absolute numbers (proportions). Source: prepared by the authors from the study data.

Following diagnostic study of each case, the most frequent discharge diagnoses in axis I were conduct disorders (43.8%) and major depressive disorder (33.6%), while in axis II the majority was personality development disorder of borderline structure (45.9%). **Table 4** shows discharge diagnoses according to axis I and II.

Table 4: Participants' diagnosis at discharge.

Diagnosis		Total sample (n = 98)	Under 10 years (n = 23)	Between 10 and 12 years (n = 36)	Over 12 years (n = 39)
Axis I	Conduct disorder	43 (43.8%)	15 (65.2%)	18 (50%)	10 (25.6%)
	Major depressive disorder	33 (33.6%)	5 (21.7%)	14 (38.8%)	14 (35.8%)
	Attention- deficit/hyperactivity disorder	26 (26.5%)	6 (26%)	17 (47.2%)	3 (7.6%)
	Attachment disorder	21 (21.4%)	7 (30.4%)	10 (27.7%)	4 (10.2%)
	Psychosis	17 (17.3%)	5 (21.7%)	8 (22.2%)	4 (10.2%)
	Psychotic episode	14 (14.2%)	5 (21.7%)	6 (16.6%)	3 (7.6%)
	Psychotic disharmony	11 (11.2%)	4 (17.3%)	4 (11.1%)	3 (7.6%)
	Neurodevelopmental disorder (non-autistic spectrum)	9 (9.1%)	3 (13%)	3 (8.3%)	3 (7.6%)
	Substance use disorder	9 (9.1%)	2 (8.6%)	5 (13.8%)	2 (5.1%)
	Impulse control disorders	5 (5.1%)	0 (0%)	5 (13.8%)	0 (0%)
	Autism spectrum disorder	5 (5.1%)	0 (0%)	2 (5.5%)	3 (7.6%)
	Bipolar affective disorder	2 (2%)	2 (8.6%)	0 (0%)	0 (0%)
Axis II	Personality development disorder	66 (67.3%)	14 (60.8%)	25 (69.4%)	27 (69.2%)
	Intellectual disability	50 (51%)	11 (47.8%)	21 (58.3%)	18 (46.1%)
	Borderline personality development disorder	45 (45.9%)	7 (30.4%)	16 (44.4%)	22 (56.4%)

Hospitalization process

The multidisciplinary team consists of child and adolescent psychiatrists, child and adolescent psychologists, social workers, occupational therapists, nurses, paramedical technicians, and assistants. In addition, there is a hospital school. The average length of hospital stay was 41.8 days (standard deviation of 31.1 days), ranging from 4 to 212 days and mode of 28 days. The management of each patient incorporated individual and family assessments, together with a complete social diagnosis. In most cases psychodiagnoses were performed with projective tests and psychometry, in addition to clinical interviews, according to clinical need (54% of cases). It should be noted that, during the hospitalization process, the average number of physical restraints was two times (standard deviation of 3.1 times) for the entire sample. Twelve patients (12.2%) received no visits during hospitalization.

Regarding psychopharmacological treatment, antipsychotics, antidepressants, mood stabilizers, and psychostimulants were primarily used. Antipsychotics were the most widely used drugs, with 98.9% of patients using at least one antipsychotic as a basic pharmacological treatment and 24.4% using two or more. Second-generation antipsychotics were mainly used. Chlorpromazine was the only first-generation antipsychotic used, being indicated as "when required" for containment or as a booster to a second-generation antipsychotic. The most commonly prescribed antipsychotic was quetiapine ($n = 45$), followed by risperidone ($n = 31$). Antidepressants were used in 59 patients, primarily selective serotonin reuptake inhibitors. The most frequently used antidepressant was fluoxetine ($n = 30$), followed by sertraline ($n = 11$). **Figure 1** summarizes the use of psychotropic drugs in the group studied.

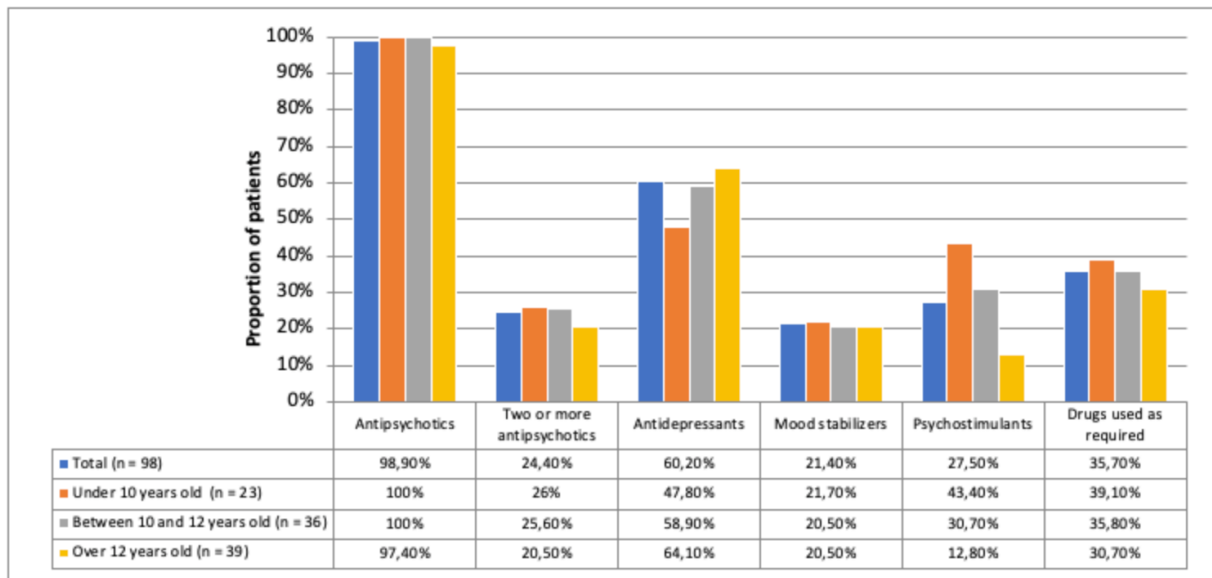


Figure 1: Proportion of patients by type of psychopharmacological agent

Clinical Evolution

Ninety-two patients continued outpatient treatment at the Del Salvador Psychiatric Hospital following discharge; 47% (n = 43) met the criteria of a good evolution, 27% (n = 25) were classified as fair and 26% (n = 24) as unsatisfactory. Twenty-one patients (21.4%) were readmitted, some of whom were hospitalized at adult's unit as they were over 15 years. Seven patients were readmitted during the first three months following discharge, all with a history of suicidal ideation and/or suicide attempt. In this group, one death by suicide occurred, six months after the initial hospitalization. Seven patients were readmitted between three months and one year of hospitalization; all were male and six presented antisocial behavior and/or were out of school.

The only factor significantly associated with an unsatisfactory clinical course was indication for an antidepressant during hospitalization (odds ratio: 4.72; 95% confidence interval: 1.3 to 16.1). Patients evidencing poor adherence to treatment, exhibited an odds ratio of 2.2 of having presented depressive symptoms (95% confidence interval: 1.2 to 3.5).

Patients who were readmitted less than three months post-discharge were at increased odds to have exhibited self-harm (odds ratio: 12; 95% confidence interval: 1.2 to 115.4) or substance use disorder on admission (odds ratio: 12; 95% confidence interval: 3.3 to 44.7). Patients

readmitted between three and six months after discharge were at increased odds of having presented suicide on admission (odds ratio: 5.6; 95% confidence interval: 1.05 to 30.8) or a substance use disorder on admission (odds ratio 6.3; 95% confidence interval: 2 to 20). The only variable significantly associated with readmission six months to one year after discharge was substance use disorder on admission (odds ratio: 4.1; 95% confidence interval: 1.5 to 11).

Treatment withdrawal during outpatient follow-up associated with behavioral disorder at discharge (odds ratio 5.2; 95% confidence interval: 1.2 to 21.8) and parental history of attempted or committed suicide (odds ratio 7.4; 95% confidence interval: 1.2 to 2.45).

Discussion

In the present study we describe characteristics of the patients hospitalized in the Short-stay Child and Adolescent Unit of the Del Salvador Psychiatric Hospital over a three-year period, analyzing factors associated with clinical evolution. The unit is organized according to a biopsychosocial approach that follows three models (Bowlby, 1975; Bronfenbrenner, 1981; Diaz, 2014; Menolascino, 1972), an eclectic and innovative perspective for this type of unit, observed in other centers in Latin America (Márquez-Caraveo et al., 2017). Most patients come from multi-problem families, of a low socioeconomic level, with a history of having suffered mistreatment and/or gross negligence and with parents that present some psychiatric pathology. Primary diagnoses were conduct disorder, major depressive disorder and development personality disorders, while substance use disorder was a factor consistently and significantly associated with hospital readmission. About half of the patients met criteria of good clinical evolution, while in one third the evolution was considered fair, and in one quarter unsatisfactory.

The first Chilean study in this area was published in 2007 by Pacheco and colleagues (Pacheco et al., 2007). It was conducted in the Child Psychiatry Unit of a university psychiatric clinic, where the prevalent clinical profile was an average age of 15 years, the primary reason for hospitalization was suicide attempt, the predominant diagnosis in axis I was major depressive disorder, and the average hospital stay was 11 days. Later, the same research group published a case-control study conducted in the same unit (Pacheco et al., 2010), where it was found that

among patients hospitalized for attempted suicide, the diagnosis of depression was more frequent.

In 2009, de la Barra and colleagues (Flora De La & Ricardo, 2009b) described the characteristics of patients hospitalized in a Children's Psychiatric Hospitalization Service in a private general hospital, where they highlighted that the most frequent reason for admission was suicidal behavior, mood disorders as the most frequent pathology of axis I and an average hospitalization of 3.8 days. In the present study, the duration of hospitalizations on average was longer than described in national (Flora De La & Ricardo, 2009b; Pacheco et al., 2007) and internacional (Bardach et al., 2014; Duarte & Zelaya, 2019; Pfeiffer & Strzelecki, 1990) literature. The need for longer hospitalizations may be explained by the high clinical complexity (Masters et al., 2014) and the social and family context (Gold et al., 1993), but also by administrative needs related to the patient's continuity outside hospital, e.g., admission to residences of the National Service for Minors, waiting for a legal resolution of proceedings in the family court, among others.

In our study, greater frequency of men differs from that observed in local research (Flora De La & Ricardo, 2009b; Pacheco et al., 2007) and abroad (Duarte & Zelaya, 2019; Hanssen-Bauer et al., 2011; Pupo-Gonzalez et al., 2018), where a greater proportion of women predominates. Our findings are consistent with research in units for children under 12, where a higher proportion of men is common (Green et al., 2007). In the current work, clinical characteristics of patients varied with age, since in children under 12 years a male profile was observed more frequently, whereby reason for admission was predominantly risk of harm to others and/or psychomotor agitation. In children over 12 years, a predominantly female profile was evident, where the most common reason for admission was risk of self-harm and the most frequent diagnosis was major depressive disorder. A highly dysfunctional social and family environment was homogeneous across age groups. In this sense, the patients studied represent severe cases, both in psychiatric pathology and in psychosocial complexity, highlighted by, for example, dropout from school. It is important to bear in mind that this unit is a tertiary referral center that attends to patients who are highly selected for their severity, with a history of multiple treatments and poor results to prior interventions.

The predominance of a profile of patients with symptomatology of the externalizing sphere, mainly behavioral, responds to the characteristics of the unit under study, since it is complex that children with this profile be managed in a pediatric ward of a general hospital. These patients require a large and safe physical space, a nursing team trained in behavioral management, especially when pharmacological and/or physical containment is part of the picture. In addition, in patients living with multi-problem families, family and psychosocial interventions are of a primary necessity. Such patients in the Valparaíso region are therefore referred to this Short-stay Unit.

In this line, it has been stated that children with severe conduct disorders present a distorted and/or deficient personality structure (Kernberg & Chazan, 2018), a statement that is consistent with the high proportion of development personality disorders found in this sample of patients. There are authors who assert that this diagnosis could not be made during adolescence, since the structure of the personality is still unstable and dynamic, therefore, the concept of "development" emphasizes a structure not consolidated in traits and permanent functioning and an identity not fully integrated (Bradley et al., 2005; Glenn & Klonsky, 2013). However, there are several studies that conclude that, despite the fact that the personality is developing, the diagnosis of development personality disorder is stable, even when made in early adolescence, between 12 and 14 years (Stepp et al., 2010), which would also allow for the visualization of earlier and more effective long-term intervention in hospitalized patients (Pacheco et al., 2007; Pupo-Gonzalez et al., 2018). Indeed, some research proposes a systematic assessment of personality structure in high-risk populations such as hospitalized adolescents, as this would be useful in case conceptualization and treatment planning (Glenn & Klonsky, 2013).

As for the admission and discharge diagnoses, differences could be explained by the team that performs them, since the admission diagnosis is given by the professionals treating the patient on an outpatient basis, while the discharge diagnosis is performed by the unit's multidisciplinary team. Likewise, it can be explained by the complexity of the social and family context of each patient, which is associated with atypical clinical presentations that are difficult to diagnose. This would explain, for example, the decrease in conduct disorder between admission and discharge, since sometimes depressive or attachment clinical pictures

may initially present as disruptive behaviors that may be confused with conduct disorders. In short, during hospitalization the patient can be observed in depth and continuously, evaluating biological rhythms, episodes of crisis and agitation, as well as interaction with peers and adults.

The sample represents multi-problem families with dysfunction, including intrafamily conflictive relationships, family breakdown, mourning, mistreatment, abuse and/or negligence. However, we do not know the extent to which this dysfunction is a symptomatic expression of episodic stress for the family due to having a sick member, or if it is a structural condition. Either way, it has been recognized that family dysfunction worsens the patient's prognosis (Sourander & Piha, 1998). More than 90% of cases presented a parent with severe psychiatric pathology, which does not consider interventions in parental skills as a therapy. During the hospitalization of their children, parents are referred for treatment if necessary and coordination is made with the treatment teams at the primary or secondary level, but there is no a treatment Unit that integrally addresses the family's psychiatric pathology. It is worth noting that 13.2% did not have a significant primary caregiver, that is, they were children who had been abandoned by their direct relatives and who lived in residences of the National Service for Minors. During the hospitalization process, an affective adult reference person is always included in the intervention to accompany the patient, even if they did not live with him/her.

In terms of pharmacological treatment, the use of antipsychotics and antidepressants predominated; 98.9% were indicated at least one antipsychotic at discharge and 24.4% received two or more antipsychotics (without considering those indicated in case of emergency). The high frequency of use may be related to the ubiquitous functions, since they are used for treatment of psychosis, mania and psychomotor agitation, among others. Quetiapine was the most widely used antipsychotic, possibly because its use in low doses (non-antipsychotic) responds to the need for psychopharmacological treatment of some insomnia conditions (Saldaña et al., 2014).

A fundamental objective of hospital interventions is improving the functioning and psychosocial adaptation to daily life. In this sense, re-schooling is essential. Of 35 patients who were not in school at the time of admission, 22 were re-schooled during the

hospitalization episode. However, re-schooling did not associate with good clinical evolution, as would have been expected.

About a third (26%) of the patients were classified as having unsatisfactory clinical evolution. The only factor significantly associated with this was indication for an antidepressant (odds ratio: 4.72; 95% confidence interval: 1.3 to 16.1). However, for those with additional depressive symptoms, odds of non-adherence to treatment were 2.2 (95% confidence interval: 1.2 to 3.5). This is consistent with existing literature (Staton, 2010).

Psychiatric hospital readmission is a frequent phenomenon in the child and adolescent population (Joyce et al., 2019), especially if the families of the patients present high levels of dysfunction, as is the case here. We worked on the basis that readmissions prior to the year post-discharge could represent relapse, while readmissions after a year might correspond to independent episodes.

Readmissions during the first three months were significantly associated with higher odds of having been admitted with risk of self-harm and substance use disorder on admission. Both factors suggest patients with higher levels of impulsivity, weaker functioning, poorer coping strategies, and more risky behaviors. There is a degree of imprecision as evidenced by large confidence intervals. Readmission at three to six months associated with presence of suicidality and substance use disorder, consistent with the findings of other studies (Bobier et al., 2005; Joyce et al., 2019). It would be prudent to consider strict follow-up in patients with suicidality, as this appears to be a strong predictor of rehospitalization (Joyce et al., 2019).

In patients readmitted between 6 months and 1 year, the impulsivity factor remains an element to be considered, since the only variable that remained significantly associated was having a substance use disorder (odds ratio: 4.1; 95% confidence interval: 1.5 to 11). It should be noted that the most frequent axis I pathology in parents was also a substance use disorder.

Within the limitations of this study, heterogeneity in diagnosis and recording clinical information is likely, and is inherent in retrospective data collection. This may have biased some results. We unfortunately could not report on the clinical evolution of patients whose follow-up was carried out in other centers. Due to the sample size, some associations may not emerge due to lack of power.

Conclusion

Child and adolescent psychiatric hospitalization is justified as an intervention when behavioral expression is maladaptive and psychopathology is severe, especially in highly complex socio-familial environments, as it is seen in the present work. Although restrictive, in these cases it could constitute an appropriate and timely therapeutic intervention for safe and effective management of acute clinical situations.

We propose, however, that child and adolescent psychiatric hospitalization units should be inserted in general hospitals and part of the community, as suggested in 2016 by the American Psychiatric Association (APA) (American Psychiatric Association, 2016) and, in 2019, by the Chilean Society of Child and Adolescent Psychiatry and Neurology (SOPNIA) (Sociedad de Psiquiatría y Neurología de la Infancia y Adolescencia (SOPNIA), 2019). Therefore, this study is not expected to be confused with validation of isolated and remote community psychiatric practice.

Notes

Author roles and contributions

MJB, FL: conceptualization, methodology, formal analysis, investigation, resources, writing (original draft preparation), writing (review and editing), visualization, supervision, project administration. JS, MB, LAD: methodology, resources, writing (original draft preparation), writing (review and editing), visualization. MA: conceptualization, methodology, formal analysis, investigation, writing (original draft preparation), writing (review and editing), visualization, supervision.

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Conflicts of interests

The authors have completed the ICMJE conflict of interest declaration form and declare that they have not received funding for the completion of this report; have had no financial relationships in the last three years with organizations that might have an interest in the published article; and have no other relationships or activities that could influence the

published article. Forms can be requested by contacting the corresponding author or the editorial board of the Journal.

Ethics

This study was evaluated and approved by the Research Ethics Committee of the Valparaíso-San Antonio Health Service (approval number 051 2017).

Second Article:

Video Feedback Intervention to Enhance Parental Reflective Functioning in Primary Caregivers of Inpatient Psychiatric Children: Protocol for a Randomized Feasibility Trial

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Abstract

Background: Children requiring hospitalization have serious disorders, high use of psychotropic medication, and frequent readmissions. The development and implementation of therapies focused on incorporating primary caregivers or attachment figures is necessary for

working with children with severe psychiatric disorders. Mentalization or Reflective Parental Reflective Functioning (PRF) is the ability of parents to understand their children's behaviors as an expression of internal emotional states and act accordingly to help them regulate their emotions, in this way mentalizing is a key component of sensitive parenting. Video assisted therapies have proven to be effective in promoting change in parent–child relationships. The majority of studies have been carried out with mothers of pre-school children and in an outpatient setting. Video Intervention Therapy (VIT) is a flexible manualized therapy, which allows the intervention to be individualized to the context where it is applied, according to the needs and resources of the people who participate in it. The objective of the study is to evaluate the feasibility and acceptability of applying VIT to improve the PRF of the primary caregivers of children hospitalized in a psychiatric service.

Methods: This is a pilot randomized, single masking (outcome assessor) with a qualitative component. It will be performing a blocking randomization procedure to generate 2:1 allocation (more people will go to intervention arm). Intervention consists of four modules; every module has both one video-recorded play session and one VIT session per week. People assigned to the control group will receive treatment as usual plus weekly play sessions. Feasibility and acceptability of the study will be addressed with quantitative and qualitative assessments. Evaluation of the caregivers will include assessments of PRF, well-being and personality structure; assessments of children will include parent- and clinician-ratings of symptomatology and general functioning. After every VF session, PRF, caregiver's well-being and children general functioning will be reassessed.

Discussion: This study will contribute to the currently scarce evidence in how to provide family attachment-based interventions in child inpatient psychiatric unit. It will also inform for designing and implementing a future randomized clinical trial.

Trial registration: ClinicalTrials.gov, NCT03374904. Registered on 14 December 2017 (retrospectively registered).

Keywords: Video Feedback Intervention, Video Intervention Therapy, Parental Reflective Functioning, Inpatient Psychiatric Children.

Background

There is a growing need for inpatient hospital beds for young children, and a corresponding shortage of supply, with increased demand for hospitalization in the last decade (Blader, 2011; Holtmann et al., 2010; James et al., 2010). In addition, hospital readmission is frequent and the disorders young children suffer from are often severe, with high use of psychotropics (Flora De La & Ricardo, 2009a; Meagher et al., 2013). This paper describes the protocol of a feasibility trial with an intervention underway that aims to lessen the family burden of hospitalization for a young child, and to improve the quality of child-parent relationships.

It has been pointed out that, compared with adolescents, younger children in psychiatric care tend to come from families with higher rates of psychosocial problems (Rice et al., 2002). There is ample evidence relating family factors with onset of psychopathology and poor outcomes in children, especially parental psychopathology (Bodden & Deković, 2016; Coates & Howe, 2016; Di Lorenzo et al., 2016; Green et al., 2007; Wang & Kenny, 2014). Even if parents lose custody of their children during hospitalization or after discharge, most of them will continue having a relationship with them and maintain contact through visits (G. Downing et al., 2013), and hopefully these children will in time return to their families as better conditions are achieved. Knowing this reality, one of the challenges when a child is hospitalized concerns how best to work with the family. This task is complicated by hospital settings (the majority) in which the psychiatric unit is not equipped to provide a bed for a parent to stay together with his/her child in hospital. This optimal pattern of hospital care, where parent and child stay together, would facilitate the delivery of dyadic treatment or family therapy. But when parents are not in the hospital, the offer of some form of family intervention is often not taken up, and when treatment begins, there is poor adherence or retention (Setoya et al., 2011).

In past decades, several attachment-based interventions have emerged, most often involving video-assisted therapy (See (H. Steele & Steele, 2018) where 15 of 21 chapters about attachment-based interventions concern early childhood interventions, the vast majority including video-feedback). Video-feedback has been shown to be an especially powerful tool in promoting change in parent-child relationships, often in just a few sessions (Facchini et al., 2016; Fukkink, 2008; Høivik et al., 2015; Rusconi-Serpa et al., 2009; Schechter et al., 2015;

M. Steele et al., 2014). It seems that video helps parents to observe themselves from the outside and by replaying the video they can obtain a more realistic and adaptive perspective on the relationship they have with their children, and the direction in which they want to take the relationship. (Høivik et al., 2015).

To the extent that seeing oneself on video is an emotional experience, it is likely that the experience, in part, activates the attachment system, calling for emotion regulation skills (Mikulincer & Shaver, 2016) that a trained therapist can help the parent to achieve. Without adequate therapeutic support, parents who are shown a video of themselves with their children may feel alternately suspicious, fearful, shamed or exhausted.

This is why in the Video-Feedback Intervention detailed below, which strongly relies on the approach of George Downing (G. Downing et al., 2013), therapists are trained never to judge a parent, and to highlight the strengths in the parent and, especially, the child. In this way nascent emotion regulations skills in parent and child, and the child's capacity to explore, are praised and nurtured. An emphasis is placed on all the good things that are evident in the parent-child interaction, but in addition to that, the therapist asks the parent whether, given the opportunity to go back in time to the moment of interaction shown on the video, would they do anything differently. A consistent theme in the therapeutic work is to focus repeatedly on the child's development and what can help the child become (more) school-ready and competent at peer relations.

The intervention also aims to promote sensitive parental behavior, understood to be based on mentalization skills in the parent. Mentalization is defined as the capacity to understand and interpret one's own behavior and those of others as an expression of mental states such as feelings, thoughts, fantasies, beliefs, and desires (Fonagy, 2002). This is based on research in parenting and child development that shows the importance of considering mental aspects underlying behavior in interactions between parents and children (Fonagy, 2002; Sharp & Fonagy, 2008). Interactions with primary caregivers who are sensitive and attuned to their needs provide infants with a sense of being held in a safe environment (Bretherton, 1992), consistent with Bowlby's definition of attachment (Bowlby, 1982). Reflective Functioning (RF) is the operational definition of mentalization and can be used to measure mentalization in

the context of an Adult Attachment Interview which is highly correlated with child attachment at 12 months (Fonagy et al., 1998; H. Steele & Steele, 2018).

Further evidence for the importance of mentalization or reflective functioning comes from studies showing that maternal sensitivity on its own is not enough to explain intergenerational transmission of secure attachment (De Wolff & Van Ijzendoorn, 1997) whereas parental mentalization has been shown to fill this transmission gap (Bateman & Fonagy, 2012; Fonagy & Target, 2005; Slade, 2005). Parental mentalizing is considered to have important implications for the development of self-regulation (Ensink et al., 2016; Fonagy et al., 1998; Slade, 2005).

The majority of research in video-feedback (VF) has been conducted with babies or toddlers although several authors have described the use of VF techniques also with older children such as preschoolers and adolescents (G. Downing et al., 2013; Whalley & Williams, 2015). In a meta-analysis (Fukkink, 2008), only six of the twenty-nine studies included children over 5 years old and the majority were small trials without control groups.

There is evidence that parental reflective functioning (PRF) relates to social adjustment and emotional regulation in preadolescents and adolescents (Benbassat & Priel, 2012; Rosso et al., 2015). Therefore, improving PRF in the period of early childhood development could contribute to the promotion of better outcomes in young people. PRF might facilitate dialogue with children and foster a deeper understanding of their needs, thus contributing to their ability to face conflict and negative emotions appropriately (Benbassat & Priel, 2012). In the context of children in psychiatric care, increasing their parents' PRF might promote the quality of their relationships, improve treatment results, and prevent future hospitalizations.

Children in inpatient psychiatric care frequently come from multi-problem families that require specific, brief, and effective interventions. The intervention proposed in the current study seeks to respond to this need. A randomized feasibility trial was designed in which a randomization was to a psychotherapeutic intervention that use video-feedback to improve Parental Reflective Functioning (PRF), during the hospitalization of children and early adolescents admitted to a psychiatric unit. The comparison group, who will not receive video-feedback will receive typical care and play sessions.

Due to the scarcity of research into the use of reflective functioning (RF) with parents of hospitalized children with severe psychopathology, a feasibility study was designed, as a first step to conducting an effectiveness study in the future. A pilot study can also identify key factors in the design and implementation of evidence-based interventions that need to be tailored specifically to the context of public health services. In this sense, a feasibility study would allow for the detection of specific strategies for the use of new therapeutic tools with parents and their children in hospital.

Aims and objectives

The objective of this paper is to report on the protocol comprising a feasibility trial of Video Intervention Therapy (VIT) to enhance Parental Reflective Function in primary caregivers of inpatient psychiatric children. As well as detailing the intervention, this paper provides an account of the plan to collect both quantitative and qualitative measurements of outcome.

Methods/design

Trial design

A small randomized controlled feasibility trial with a qualitative component has been designed to assess feasibility and acceptability of a brief video-feedback intervention, and to collect parameters that may serve as the rationale for the implementation of a large RCT in the future. See Figure 2.

Settings and participants

The research will take place in a public child and adolescent psychiatry ward in Valparaíso, “Hospital Psiquiátrico del Salvador”. The quantitative aspect of the study will be conducted with caregivers of children aged 6 to 14 who are hospitalized in a child and adolescent psychiatry ward from August 2017 until complete sample size, that is expected by December 2018. The sample will be comprised of all parents and/or caregivers who meet the inclusion criteria, do not meet the exclusion criteria, and who agree to participate. The expected sample size is 30 subjects in total: 10 for the control group and 20 for the experimental group. It was chosen a 2:1 allocation for collecting more data regarding acceptability of participants and feasibility of delivering the intervention.

Inclusion Criteria

The participant must be registered as a tutor during hospitalization or registered as the primary caregiver of the child or adolescent and has a legal or biological kinship with the hospitalized child or adolescent.

Exclusion Criteria

Participants will be excluded if they are:

- Caregivers with severe intellectual deficit or psychotic symptoms
- Foster caregivers or institutional caregivers
- Parents who do not care for the child regularly (for example: they visit the child less than one week per month or has restraining orders)

For the qualitative component of the study, a minimum of six primary caregivers of psychiatric inpatient children who participated in the VIT intervention will be interviewed, as well as three key stakeholders: a therapist, a nurse and the chief psychiatrist of the Special Care Unit.

Power calculation

As a feasibility study, no hypotheses will be tested and, therefore, formal power calculation is not appropriate (Eldridge, Chan, Campbell, Bond, Hopewell, Thabane, Lancaster, & PAFS consensus group, 2016; Leon et al., 2011). The unit where the research will take place has an average of 60 inpatient children per year, with almost half of these children in foster care and, therefore, with institutional caregivers who are not included in the study. Based on the feasibility of recruitment, we aim to have 30 participants in order to estimate key parameters for a future RCT to be based in large part on the primary outcome of the feasibility and acceptability trial, i.e., the caregivers' reports of what was felt to be clinically useful or meaningful.

Treatment

Control Group (TAU + Play therapy)

All patients and their families will be receiving standard care in a child and adolescent inpatient unit (Ministerio de Salud & Asistenciales, 2016), which mainly focuses on the child's individual symptoms and problems and includes pharmacological and daycare management, occupational therapy, crisis intervention, and psychological counseling.

As all patients receive dyadic play therapy once a week in the company of their tutors, and only some of these pairs are invited to participate in VIT, dyadic play therapy will be the active comparator to VIT. Play sessions have a workshop format, where the caregiver plays freely with the child for each 45- to 60-minute session. The type of play varies according to the child's needs and developmental stage. There is a box of toys available for the children to explore and role play with their caregivers or play rule-based board games. Occasionally, young adolescents and their caregivers are invited to negotiate regarding a particular topic (e.g., time permitted for technology), plan a day off, or think through what the routine on discharge will be. The type of play or the activities chosen are flexible, according to the child's and caregiver's particular needs detected by the therapists (Fukelman et al., 2015b). Therefore, sessions consist of dyadic play interactions with tutors or other caregivers who are being coached by a therapist in promoting child-oriented and healthy social interactions. Five to ten minutes of these play sessions are video recorded.

Intervention arm – Video Intervention Therapy (VIT)

VIT is a technique for performing video feedback where behavior-oriented interventions and representational therapy elements are used (G. Downing et al., 2013; Høivik et al., 2015), providing a six-step video-analysis framework. Videos can be filmed at different settings, with the only requirement being an observable interaction of the child with his caregiver(s) where the full bodies and faces of all participants are ideally captured on the film (G. Downing et al., 2013; Facchini et al., 2016).

A four-module intervention was designed for this study. Each module includes a play session and a VIT session. First, a play interaction between the child and caregiver is recorded (5 to 10 minutes) during play therapy sessions. Then, the therapeutic team chooses approximately 1- to

2-minute-long excerpts to display in VIT sessions. VIT occurs during the same week of play therapy and VIT excerpts are shown to groups of caregivers, unless there is only one study participant at that time. When VIT excerpts are shown in groups, caregivers view excerpts of multiple children, not just their own, and actively participate in the session. Interventions will be performed by the researcher and by a clinical child psychologist, both trained and supervised. The therapist prepares the feedback session to show positive interactions first. Then, if the caregiver is willing and psychologically prepared to explore problematic patterns that can be modified, the therapist further discusses these interactions with the caregiver. During the sessions, the therapist may shift focus based on real-time comments, questions, and the group dynamic. The first session of VIT is centrally focused on building rapport with the caregiver, and reinforcing observed strengths of the caregiver, of the child, and of the caregiver-child relationships. The caregiver learns the immediate and longer-term developmental goals for the child from the therapist and other parents. Other caregivers or parents have a unique supportive role to play in VIT group sessions because of their peer status. Sometimes caregivers could spontaneously talk about something problematic that they would do differently if they were in that moment again, and sometimes therapists ask the parents if they want to see something that they could do differently (negative pattern), if the caregivers agree, they take a deeper look into the negative patterns using mentalization techniques. The cardinal virtue for the therapist of assuming a non-judgmental stance rests at the core of VIT work (G. Downing et al., 2013).

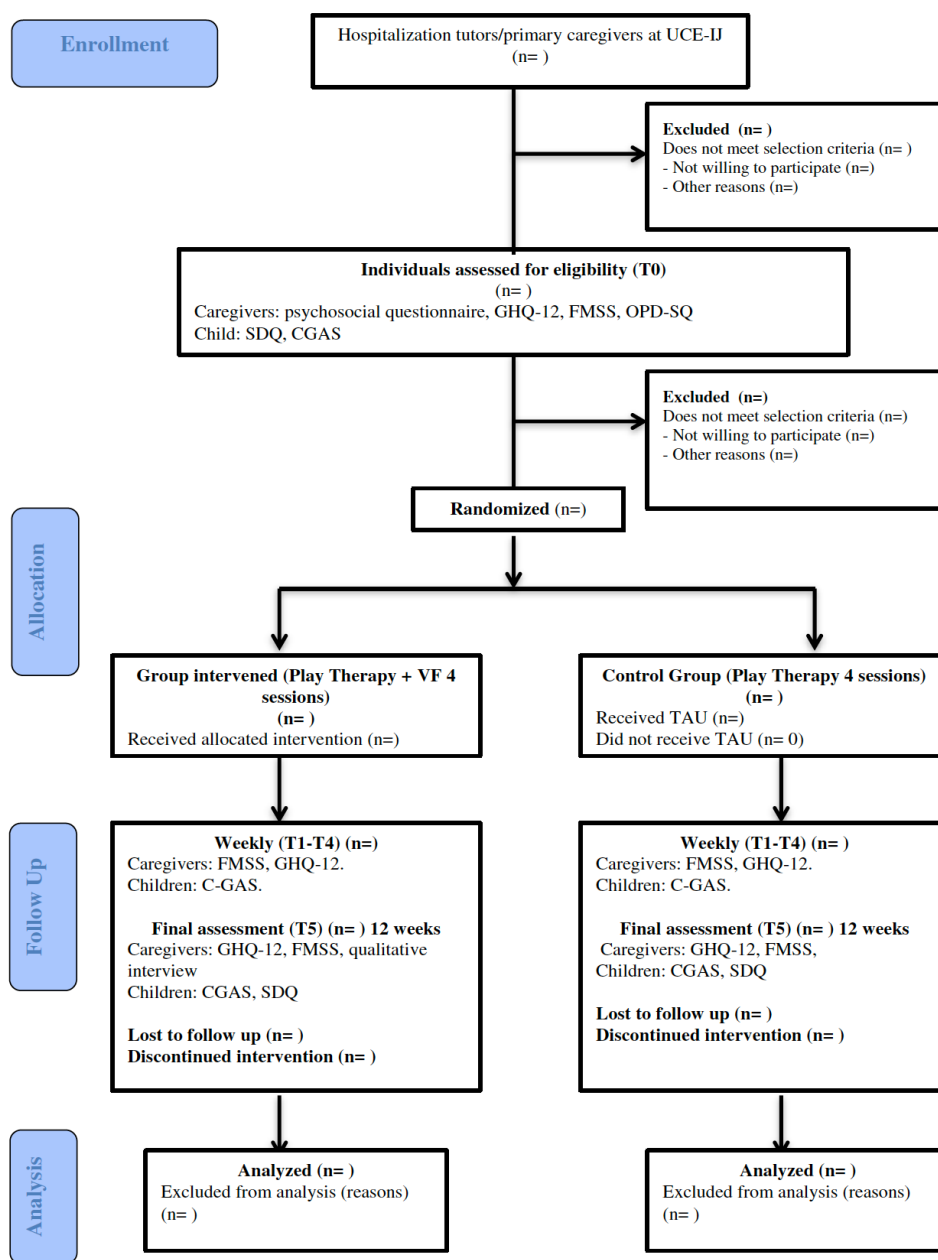


Figure 2: Flowchart of study phases and instrument application.

Procedure

Eligible participants will be caregivers of children in an inpatient unit. All caregivers who are referred to play therapy and meet inclusion criteria will be invited to participate in the VIT study by a professional of the unit staff, and they will be interviewed by one of the therapists to explain the study. Informed and written consent will be obtained from caregivers and assent

from children and adolescents participating in the study before entry evaluation is done. The study includes the use of self-report questionnaires and a samples of recorded caregiver monologues about their child, which are recorded in private, to assess parental reflective functioning.

Randomization and masking

An external researcher will use a random number generator to perform a blocking randomization procedure, then will create a list of participants before inclusion of the first participant to provide allocation of 2:1 in order to have a higher number of participants in the VF intervention and to have a similar proportion during the year of caregivers in both arms. The clinical team is not aware of the blocking procedure, but the main research it is, to avoid biases the other member of the clinical team are in charge of allocation of the caregivers. When a participant finishes the entry evaluation the external researcher will inform to the clinical team regarding the corresponding allocation.

Although participants and care providers will be aware of treatment allocation, encoders of PRF will be masked to this (outcome assessor masking). Transcriptions will be anonymous in order to mask the caregivers' identity and whether they belong to the control or the intervention group. Three highly trained encoders, who are outside the therapeutic context, will analyze the interviews to ascertain the level of PRF.

Outcomes

Feasibility parameters

The feasibility will be evaluated in terms of eligibility rates, recruitment rates and reasons for study refusals, data attrition, and follow-up rates by treatment condition.

Acceptability of intervention

Participant-attendance rates, and caregivers' and key stakeholders' qualitative assessment of the intervention acceptability and satisfaction with the intervention. Acceptability will be evaluated in terms of attendance rates and through a qualitative assessment from caregivers and key stakeholders of the intervention acceptability and satisfaction.

Secondary Outcomes

The secondary outcomes will be demographic and mental health status at baseline and change over time in PRF, caregiver's well-being and children symptoms and general functioning.

Instrument description

Figure 3 shows the schedule of assessments.

1. Five Minute Speech Sample (FMSS) (Gottschalk & Gleser, 1969) for evaluating Parental Reflective Functioning (PRF).

- In this instrument the caregiver is asked to talk about the child for five minutes without interruptions. This monologue is audio-recorded for future codification. A FMSS for each caregiver will be recorded at the beginning of the study and prior to each session. The FMSS has been used for over thirty years to assess Emotional Expressiveness of parents towards their children (Sher-Censor, 2015), but over the past years its use as a tool for assessing parents' or caregivers' reflective functioning has increased progressively (Adkins et al., 2018; Bammens et al., 2015). RF levels are obtained by coding the transcription according to the Reflective Functioning Evaluation Manual with a scale that goes from -1 (avoidance or rejection of mentalization) to 9 points (complete or exceptional RF). A score of 5 indicates a clear understanding of mental states. The RF scale reliability after training is usually high, with correlations reported from 0.81 to 0.94 (Benbassat & Priel, 2012; Bouchard et al., 2008; Rosso et al., 2015). To date, there are no studies published in Chile that use the FMSS.
- The FMSS will be coded by certified psychologist with training in RF coding. To obtain inter-judge reliability in this sample, three coders will code 20% of the full set of FMSSs, i.e. 36 of the 180 to be collected (Adler et al., 2017). The 36 FMSSs to be included in this test of inter-observer agreement will come more-or-less equally from each of the six assessment periods (6 from each time period when PRF will be assessed).
- This tool will be applied upon entering, after each VIT session, and at the end of the study.



	STUDY PERIOD								
	Enrolment	Baseline	Allocation	Post-allocation					Close-out
TIMEPOINT	$-t_1$	t_0		t_1	t_2	t_3	t_4	12 weeks	18 months
ENROLLMENT:									
Eligibility screen	X								
Informed consent	X								
Allocation			X						
INTERVENTIONS:									
<i>Play Therapy + TAU</i>									
<i>VIT + Play Therapy + TAU</i>									
ASSESSMENTS:									
Quantitative									
<i>FMSS</i>		X		X	X	X	X	X	
<i>OPD-SQ</i>		X							
<i>GHQ</i>		X		X	X	X	X	X	
<i>SDQ</i>		X					X	X	
<i>CGAS</i>		X		X	X	X	X	X	
<i>psychosocial questionnaire</i>		X							
<i>Qualitative data from caregivers</i>								X*	
<i>Qualitative data from stakeholders</i>									X

Figure 3: Schedule of enrollment, interventions and assessments.

2. General Health Questionnaire (Goldberg, 1972). GHQ-12

- Araya et al validated this self-report questionnaire in Chile (Araya et al., 1992) and is widely used in Chile as a screening test for depression and general psychopathology (Ministerio de Salud Subsecretaria de Salud Publica, 2013). In order to assess a

person's wellbeing, this instrument targets two areas: the inability to carry out normal functions and the appearance of distress (Goldberg, 1972), Total scores range from 0 to 36.

3. Operationalized Psychodynamic Diagnosis – Structured Questionnaire (OPD-SQ).(J. Ehrental et al., 2012; J. C. Ehrental et al., 2015)

- The OPD-SQ self-report instrument measures the level of structural integration of personality through the evaluation of four main dimensions, which in turn can each be directed towards two orientations:
 - i. Perception (of self and objects)
 - ii. Management (of self and relations)
 - iii. Emotional Communication (internal and external), and
 - iv. Linkage (internal and external relationships).
- In each of its 95 items participants indicate the degree to which they feel accurately described in a 5-point Likert scale. The average of all items is an indicator of the global structural functioning, where higher scores indicate less structural integration. This instrument has been translated into Spanish and has been used amongst Chilean clinical populations (de la Parra et al., 2018).

4. Children Global Assessment Scale (CGAS) (J. Ehrental et al., 2012; Shaffer et al., 1983)

- CGAS is a clinician-rated tool used to assess general functioning of children aged 4 to 16. Scores range from 1 (the most impaired level) to 100 (superior functioning). Scores above 70 are considered to be near normal functioning (Shaffer et al., 1983). This tool is commonly used by mental health clinicians in naturalistic settings and in research (Lundh et al., 2010; Stefanovics et al., 2014). Having been translated into Spanish, it is a valid and reliable scale both in time (ICC =.44) and across evaluators (ICC =.81) (Ezpeleta et al., 1999).

5. Strengths and Difficulties Questionnaire (SDQ) (Goodman, 1999).

- This self-report screening questionnaire assesses psychopathology in children and adolescents between the ages of 4 and 16. It can be completed by parents and/or teachers and takes approximately 5 to 10 minutes to fill in. Each item is scored 0, 1 or 2 according to a Likert scale in three categories: not true, true, and absolutely true. It also considers items that assess the child's strengths, in which the scoring is inverted (0: absolutely true and 2: not true). This instrument has been validated in several countries showing good reliability. In Chile its psychometric properties for the parent population have been evaluated, showing good reliability in the total score and an internal consistency of $\alpha = 0.79$.

6. Sociodemographic survey

- A survey will be prepared according to the study's aims, including individual and family data as registered upon patient entry to the Special Child Care Unit. Data will consider aspects such as age, parents' educational level and employment status, children's school achievements and failures, prior medical and/or psychiatric treatment, among others.

7. Participants interviews

- An open-ended set of questions to be put to caregivers at the end of the intervention. These questions include:
 - i. What did they think was useful about the intervention?
 - ii. What difficulties did they experience with engagement with the intervention?
 - iii. Do they think their relationship with their child was changed by the intervention?
 - iv. How did they experience the hospital treatment?
- These will be asked of the caregivers, at the end of the intervention, to gain a picture of the acceptability of the intervention and will be analyzed quantitatively.

8. Stakeholder interviews

- One of the therapists delivering the intervention will be interviewed with open-ended questions regarding aspects needed to be considered for the delivery of the intervention, such as time needed to prepare the session, how much supervision is required, etc. In addition, the chief psychiatrist and the unit charge nurse will be interviewed. Both will be asked about factors that they consider critical for implementing the intervention and what consequences in the functioning of the unit are observed during the development of the trial.

Data collection

All participants will be assessed at baseline, immediately after every VIT session (after every play session for the control group) and three months after recruitment (**Figure 3: Schedule of enrollment, interventions and assessments.**). There is no economical compensation for participating in this trial.

Safety monitoring and criteria for discontinuation

It is not predicted that there may be negative effects for the participants. Although any participant in a psychotherapeutic intervention might experience intense emotions, these will be addressed during the session. If it is detected through the questionnaires or by clinical criteria that some of the participants present mental health problems, they will be referred to the corresponding health center. Participants may withdraw from the study at any time without any impact on the regular treatment their children are receiving on the inpatient unit.

Data analyses

Qualitative Study

The information obtained from the caregivers' and key stakeholders' interviews will be analyzed using Grounded Theory (Corbin et al., 2008). ATLAS.TI v7 software will be used for analyzing the data, as it enables managing and processing groups of text data.

Quantitative Study

The quantitative study will be conducted as follows:

1. Descriptive statistics will be used for evaluation of the clinical and sociodemographic variables in the control and intervention groups. The mean and standard deviation (SD) will be calculated for continuous data and numbers and percentages will be calculated for categorical data.
2. Descriptive statistics of eligibility rate and recruitment rate for the full sample; adherence, data attrition and follow-up rates will be presented by treatment group.
3. The completion rate and missing data will summarize for all variables.
4. Change over time in PRF, GHQ, SDQ and CGAS will be assessed graphically per group using tangled line or spaghetti plot, displaying individual trace for each subject per group. Also, it will display the mean per group.
5. Estimates and variances for PRF, GHQ, SDQ and CGAS, to determine the most appropriate primary outcome measure for a definitive trial.

Data and presentation of the results will be in accordance with CONSORT extension guidelines for randomized pilot and feasibility trials (Eldridge, Chan, Campbell, Bond, Hopewell, Thabane, Lancaster, & PAFS consensus group, 2016).

Research governance and ethics

Trial management

The study will comply with local research governance requirements.

Ethics

Full ethical approval was obtained from the local Ethics Committee (Comité Ético Científico del Servicio de Salud Valparaíso- San Antonio, ORD 1502, 8 August 2017).

Discussion

The study addresses an important gap in the knowledge on how to provide effective interventions for caregivers of psychiatric inpatient children. As far as we know, children in need of inpatient psychiatric care come from multi-problem families in which most caregivers also suffer from mental disorders and in many cases do not receive any treatment (Bodden & Deković, 2016; Rice et al., 2002). Considering this context, a brief, effective, attractive, and

low-cost intervention is required. Video-feedback interventions primarily focus on caregivers' resources and strengths, facilitating the establishment of rapport with participants and promoting their attendance. Not being criticized and feeling they can effectively take care of their children, can be a new and attractive experience for them that promotes self-efficacy as a parent. The end-of-treatment interviews with parents will explore the range of reactions parents have had to the intervention.

Although these interventions can be beneficial when working with parents of children in psychiatric care, not all evidence-based interventions can be easily implemented in public psychiatric health services for different reasons. Clinical teams might present resistances to modifying the type of interventions they are accustomed to using due to lack of training, difficulties in accessing the necessary training or concerns regarding the interventions' usefulness in naturalistic settings. For these reasons, the stakeholders are being interviewed.

This pilot study seeks to demonstrate that it is feasible to develop an innovative, manualized and potentially effective intervention for multi-problem families who have their children hospitalized in a public psychiatric service. This pilot trial will inform in how to conduct a future trial in order to assess the effectiveness of VIT in improving Parental Reflective Functioning (PRF), psychiatric symptomatology in children, and parent-child interactions. Likewise, future research in this area can explore further the relationship between PRF and child psychopathology (Fonagy et al., 1998), and the specific role that video feedback may play in promoting PRF (M. Steele et al., 2014).

Trial status

Recruiting of patients into the study began in August 2017. Recruitment ended in February 2019.

Abbreviations

PRF: Reflective Parental Functioning, VIT: Video Intervention Therapy, RCT: Randomized Clinical Trials, FMSS: Five Minute Speech Sample, GHQ General Health Questionnaire, OPD-SQ: Operationalized Psychodynamic Diagnosis – Structured Questionnaire, CGAS: Children Global Assessment Scale, SDQ: Strengths and Difficulties Questionnaire.

Declarations

Ethical Approval and Consent to participate

Full ethical approval was obtained from the local Ethics Committee (Comité Ético Científico del Servicio de Salud Valparaíso- San Antonio, ORD 1502, date 8-8-17). The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (1996) and the principles of Good Clinical Practice (such as data storage and administrative functions).

Written informed consent will be obtained from participants in the study (adults and children). Participants will be free to withdraw from the study at any time without giving a reason and without their care being affected. All the information collected during this trial will be confidential.

Interviews which are transcribed will be anonymized at the point of transcription. Any third party involved with transcribing of interviews will sign a confidentiality agreement and be fully instructed in how to anonymize transcripts.

Consent for publication

Not applicable.

Availability of supporting data

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

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

FL and MO conceived the study and are involved in managing and advising the project. RA, GR, LD, GD and HS are contributing to the development of the project. All authors contributed to the drafting of this paper and approved the final manuscript.

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Authors' information

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Trial registration

NCT03374904. Registered on 14 December 2017 - Retrospectively registered, <https://clinicaltrials.gov/ct2/show/NCT03374904>

Third Article:

Video Intervention Therapy for Primary Caregivers in a Child Psychiatry Unit: A Randomized Feasibility Trial

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ABSTRACT

Background: During child psychiatry hospitalization, working with the families or attachment figures is a challenge, most of the children who are admitted to these units come from multi-problem families, with limited research in this area. Video Feedback (VF) intervention have proved to be a powerful resource to promote parental and child wellbeing in small children and has been used with parents with a psychiatric condition. Parental Reflective Functioning (PRF) is one of the parental abilities that can be improved with VF and could be especially important in coping with conflict and negative emotions in older children. The aim of this study is to implement Video Intervention Therapy (VIT) to enhance PRF in primary caregivers of inpatient psychiatric children. As there is no published research using VF with parents of children with severe psychopathology in a hospitalized context, this becomes a much-needed pilot study providing evidence for a larger randomized control trial (RCT).

Methods: The study is a single center, two-arm feasibility randomized control trial with a qualitative component. Block randomization was done to generate a 2:1 allocation, leaving more participants in the intervention group. The intervention comprises four modules; every module has both one video-recorded play session and one VIT session (in a group setting) per week. Evaluation of the caregivers included assessments of PRF and wellbeing, child assessment included parent-ratings and clinician-ratings of symptomatology and general functioning.

Results: Thirty participants were randomized; eligibility and recruitment rate were 70.6% and 83.3% respectively. Compliance-to-intervention rate was 85% in the VIT group and 90% in the control group. All participants completed entry evaluation and 90% at 3 months follow-up. The intervention was acceptable to participants and feasible for therapists to deliver. Outcome data must be treated with caution due to the small numbers involved yet indicate that the VIT may have a positive effect in improving parental and child mental health outcomes.

Conclusions: VIT for primary caregivers of child inpatient children was feasible to deliver and acceptable for participants, therapist and the staff unit involved, there is sufficient evidence to undertake a full-scale effectiveness RCT.

Trial registration: ClinicalTrials.gov, NCT03374904. Registered on 14 December 2017

Keywords: Video feedback intervention, Video intervention therapy, Parental reflective functioning, Inpatient psychiatric children.

BACKGROUND

Hospitalization in child psychiatry services is the most specialized and expensive step in the pyramid of interventions available to treat severe psychiatric problems in children. Admitting a child should be the last resource not only because of the costs involved, but also because separating the child from his/her usual environment (family, peer group and community) may be detrimental to the child's development (Polan & Hoffer, 2016) and the costs and benefits of hospitalization should be analyzed on a case-by-case basis. Nevertheless, there is a growing need for beds and admission rates have increased in the last decades (Blader, 2011; Holtmann et al., 2010; James et al., 2010).

In countries enjoying community mental health care systems, referral of children and young adolescents to hospitalization occurs when there is a lack of response to outpatient treatments. Most of those children have mental disorders compounded by co-morbidities including learning and developmental problems (Oliveira et al., 2014). These children generally live among multi-problem, at-risk families, characterized by parental mental health problems, socioeconomic difficulties, addiction, history of abuse and neglect, among other problems (Barker et al., 2020; Gathright et al., 2016; Rimehaug, 2019).

There is a wide range of family interventions, all of which are effective in managing child mental health issues (Sharma & Sargent, 2015) in an ambulatory context. Any pediatric psychiatric hospitalization unit must necessarily intervene not only with the child, but also with their family. The best way to do this remains an open question. A recent review of evidence-based family interventions in child psychiatry, where the authors summarize 15 years' worth of randomized controlled trials (RCT) results, indicates certain research opportunities in the area given that there is no mention of any RCT in a hospital setting (Sharma & Sargent, 2015). There are different ways to respond to this need in each unit's "milieu", including inpatient family units, where one or more members of the family are hospitalized together with the child, where a variety of family interventions (Ise et al., 2015; Rimehaug, 2019), and elements of a family-centered care approach are applied (Jolley & Shields, 2009).

There are few studies about family interventions in inpatient setting, two of them that evaluate the effectiveness of units where the children were admitted with their families, both concluding that mental health of children and parents improves when using this approach. A limitation of these studies is that because each evaluated the unit in its entirety, a control group was not implemented (Ise et al., 2015; Rimehaug, 2019). A third study implemented universal parent training during the child's hospitalization and at three-month follow-up. A positive effect was seen as dysfunctional parenting was reduced and parental mental health improved, but no effect on the children's symptoms or the quality of interaction between the children and their parents were found (Schwenck et al., 2016).

A family or parental intervention during a child psychiatric hospitalization should obviously be effective, but also brief, focused, long-lasting and tailored to child and family needs and

resources. There are three meta-analyses that demonstrate intervention effectiveness, using Video Feedback (VF) techniques, by improving parental behavior and relationship between parents and children (Bakermans-Kranenburg et al., 2003; Fukkink, 2008; O'Hara et al., 2019). The studies included in these reports mostly include parents of children under 5 years of age, without severe mental health pathologies.

A pilot clinical trial was designed to adapt a VF intervention for use during hospitalization and to evaluate future effectiveness. The use of Video Intervention Therapy (VIT) was used since it is a flexible manualized VF intervention, adaptable to different settings and family contexts. VIT aims to enhance Parental Mentalizing or Reflective Functioning (PRF) (George Downing, 2008; George Downing et al., 2013a; H. Steele & Steele, 2018). Parental Mentalizing refers to a cognitive and emotional process of reflection on the internal mental states of the adult and child in order to regulate the emotional state and act sensitively to the needs of the child (Fonagy et al., 1991; Fonagy & Target, 1997; Slade, 2005). Mentalizing has been operationalized in Reflective Functioning, which can be measured by coding answers to questions that activate the attachment system (Fonagy et al., 1998). It is expected that parents who improve their PRF would not be afraid to reflect on their children's mental states (thoughts, emotions, desires among others), becoming curious and interested in the different facets of their offspring. They are also expected to develop, through a better internal dialogue, a greater capacity for emotional regulation, which at the same time would allow them to anticipate crisis situations and respond to them in more constructive ways.

The current study

The objective of this current study is to realize a pilot Randomized Controlled Trial (RCT) to evaluate a Video Intervention Therapy (VIT) to enhance Parental Reflective Function in primary caregivers of inpatient psychiatric children, to assess feasibility and acceptability, and to provide data to estimate parameters required to design a definitive RCT as the next step.

METHODS

The protocol describing the methods in detail was previously published (Leyton et al., 2019), the trial was retrospectively registered on ClinicalTrials.gov NCT: 03374904. This feasibility trial is reported with the Consolidated Standards of Reporting Trials (CONSORT) guideline

for pilot trials (Eldridge, Chan, Campbell, Bond, Hopewell, Thabane, Lancaster, O’Cathain, et al., 2016). Full ethical approval was obtained from the local Ethics Committee (Comité Ético Científico del Servicio de Salud Valparaíso- San Antonio, ORD 1502, date 8-8-17).

Trial design

The study was conducted from August 2017 to April 2019, being a single-blind, parallel, two-arm, feasibility RCT. Participants were randomized to either an Intervention Group (4 weekly sessions of Dyadic Play Therapy PT and four weekly sessions of VIT for caregivers) or a Control Group. Also, a nested qualitative study evaluating perceptions held by caregiver, therapist and mental health workers was performed.

Settings and participants

Participants were recruited from a public child and adolescent psychiatry ward in Valparaíso, Chile, during August 2017 to February 2019. Inclusion criteria were: 1) being registered as a tutor or primary caregiver during child hospitalization and 2) having a legal or biological kinship with the hospitalized child or adolescent. Exclusion criteria were 1) being foster caregivers or institutional caregivers or, 2) having a severe intellectual impairment or, 3) having psychotic symptoms, or 4) parents who do not provide regular childcare.

Recruitment procedure

Eligible tutors were invited to participate in the study by a staff member (usually psychologist, occupational therapist or psychiatrist). Informed and written consent were obtained from caregivers and assent from children participating in the study, following from this a baseline evaluation was carried out.

Sample size

Thirty participants were recruited, the sample size was not chosen to achieve a level of statistical significance, but rather to define key parameters, including feasibility and acceptability, aiming to justify a future and larger RCT (Smith & Harrison, 2009).

Randomization and masking

An external researcher performed a blocking randomization procedure using a web-based random number generator. Participants were allocated in a 2:1 fashion, placing the higher number of participants in the Intervention Group and similar proportions of caregivers in both study arms during the 18-month study period. Only the main investigator, who was also one of the psychiatrists and VIT therapists, was aware of the blocking procedure.

After an entry evaluation was completed in each case, the clinical team was informed by an external researcher as to which allocation that dyad corresponded to.

Three reliable coders, who were masked (outcome assessor masking) and not immersed in the therapeutic context, evaluated PRF level. Caregivers' identity and allocation group were unknown.

Interventions

Both Interventions were performed by two therapists at a time.

- 1) Play Therapy:** all patients and their tutors received weekly dyadic free-play therapy in a 60-minute workshop format, coached by a therapist to promote child-oriented and healthy social interactions. A box of toys was available for the children to explore and role play with their caregivers. Also available were rule-based board games and other materials to draw and craft. Games and toys varied according to the child's preferences and developmental stage (Fukelman et al., 2015a). For early adolescents, the therapists encouraged conversations between caregivers and their children, for example negotiation regarding certain topics (e.g., routine at home visits, and eventual discharge).
- 2) Video Intervention Therapy (VIT)** is a six-step Video Feedback technique that uses behavior-oriented interventions and elements of representational therapy (George Downing et al., 2013a). Videos can be filmed at different settings, with the only requirement being an observable interaction of the child with their caregiver(s) (Facchini et al., 2016).

Intervention Group (Play Therapy + VIT)

The study includes a four-module intervention, each module contains a play session and a VIT session. During play therapy a 5 to 10-minute film excerpt was made of a child and caregiver interaction. The therapeutic team would then choose approximately 1- to 2-minute-long excerpts to display in latter VIT sessions. VIT occurs during the same week of play therapy and VIT excerpts are shown to groups of caregivers, unless there were only one study participant at that time. When VIT excerpts are shown in groups, caregivers view film excerpts of multiple children, not just their own, and actively participate in the session.

The first session of VIT is centrally focused on building rapport with caregivers and reinforcing their observed strengths as seen on the video. The caregiver learns the immediate and longer-term developmental goals for the child from the therapist and other parents. Other caregivers or parents have a unique supportive role to play in a VIT group session because of their peer status. Caregivers, when looking at the videos, may spontaneously talk about something problematic or that they would do differently if they were to find themselves in that situation once again. In other cases, therapists may ask parents if they would want to see something that they may do differently (“negative pattern”). If caregivers agree, they take a deeper look into a negative pattern, using mentalization techniques. The cardinal virtue for the therapist is to assume a non-judgmental stance in working with VIT (George Downing et al., 2013a).

Control Group (TAU + Play therapy)

Treatment as usual (TAU) includes pharmacological and daycare management, occupational therapy, crisis intervention, psychological counseling and family assessments and support as needed (Barker et al., 2020). Besides that, the participants in the control group received weekly dyadic play therapy sessions as described previously.

Outcomes

Feasibility parameters

1. Eligibility rates: proportion of hospitalization tutors meeting the eligibility criteria.

2. Recruitment rates: proportion of participating caregivers, to include reasons for declining to participate.
3. Data attrition rate: Estimates the proportion of complete entry evaluation by participant and after every session by treatment group.
4. Follow up rate: Estimates the proportion of participants completing a 3-month follow-up assessment, per treatment group.
5. Key stakeholders' qualitative assessment regarding intervention, implementation and delivery.

Acceptability of intervention

1. Participant-attendance rates: Proportion of participants that complete the VIT intervention (4 sessions)
2. Qualitative assessment of the intervention made by caregivers regarding acceptability and satisfaction.

Secondary Outcomes

Demographic and mental health status at baseline and changes over time in PRF, the well-being of caregiver, child symptoms and general functioning.

Instruments

A detailed description for the chosen measures is provided in the published protocol.

Caregiver assessment includes:

1. Sociodemographic survey to collect data on the caregiver, child, and family system.
2. Five Minutes Speech Sample (FMSS) (Gottschalk & Gleser, 1969) to assess Parental Reflective Functioning (PRF) with the Reflective Functioning Evaluation Manual (Fonagy et al., 1998) that scores PRF in a scale from -1 to 9, 9 being an exceptional PRF. The FMSS was coded by three certificated psychologists with training in Reflective Functioning Scale (RFS) coding. To obtain inter-judge reliability in this sample, all coders coded 20% of the full set of FMSSs. Inter-observer agreement was evaluated with interclass correlation (ICC), obtaining a value of 0.71.

3. General Health Questionnaire-12 (GHQ-12) (Araya et al., 1992; Özdemir & Rezaki, 2007) was used to assess parental well-being with a score from 0 to 36, higher scores indicating a lower level of well-being.

Child assessment includes:

1. Strengths and Difficulties Questionnaire (SDQ) (Brown et al., 2014; Goodman, 1999) to assess psychiatric symptoms according to caregivers, consisting of 25 items, each uses a 3-point ordinal Likert scale (0: “not true”; 1 “somewhat true”; 2 “certainly true”). Responses are rated 0–2 for negatively worded items and are rated inversely, 2–0, for positively-worded items, giving a total score (SDQ-tot) ranging from 0 to 40, where a lower score means less symptoms. In addition, two subscales were used; the one for internalizing symptoms (SDQ-int) regarding emotional and peer items and the one for externalizing symptoms (SDQ-ext) which includes behavioral and hyperactivity items.
2. They were also rated with the Children’s Global Assessment Scale (CGAS) (Ezpeleta et al., 1999; Shaffer et al., 1983) to evaluate general functioning according to therapists, with scores ranging from 1 (most impaired) to 100 (superior functioning).

Qualitative interviews

1. Participants: At the end of VIT intervention (four completed modules) participants were asked to give an interview, lasting from 30 minutes to 1 hour, conducted by an external researcher. The interview was an open-ended set of questions to explore in-depth caregiver experience regarding intervention acceptance, why they agreed to participate, how they felt as the intervention unfolded, and any workshop difficulties or weaknesses in the format, also explored were changes in the child-caregiver relationship, emergence of new ways of thinking about the child and themselves as parents. The interviews were conducted face-to-face in hospital facilities.
2. Therapists: They answer a one-hour long interview exploring their experience in intervention delivery, including any time, space, supervision and collaboration requirements from the in-patient clinical team.

3. Key Stakeholders: A nurse, two psychiatrists and a paramedic were interviewed for 30 to 45 minutes exploring their experience while the trial was conducted, they were asked to report on their intervention impressions and how the trials impacted the regular in-patient unit functioning. Therapists and Key stakeholder interviews were carried out after the last participant finished the trial.

Data collection

All participants were assessed at baseline, immediately after every VIT session (or after every play session for the control group) and three months after recruitment. There was no compensation given for participating in this trial. Only the SDQ questionnaire was completed at baseline, post-treatment and a 12 week follow up.

Data analysis

Statistical Analysis

Means and standard deviation, for the whole sample, per main outcomes are presented for both control and experimental groups at baseline, at the end of intervention and after the three-month follow-up. The data sets analyzed consisted of 21 cases, having to exclude all those who dropped out of the study (seven cases), plus a further two excluded due to protocol breaches, (one control group participant, and one from the intervention group). An Analysis of Covariance (ANCOVA) was performed to assess between-group mean differences at the end of the intervention and at follow-up, using the baseline as a control variable. Mean change score differences were calculated through t-tests for related samples by comparing baseline-post intervention and baseline-follow up. In accordance with pilot study recommendations (Eldridge, Chan, Campbell, Bond, Hopewell, Thabane, Lancaster, O’Cathain, et al., 2016), confidence intervals and effect sizes are presented. In the ANCOVA analysis, due to biases regarding the Partial η^2 statistics (Barton & Peat, 2014), effect sizes were converted to Cohen's f , through G-Power 3.1. (Faul et al., 2009). To facilitate result interpretation, contrast analysis mean differences between groups are shown once the baseline scores were controlled. All descriptive and inferential analyses were performed through JASP software, version 0.8.6 [computer software].

Qualitative analysis

Grounded Theory model was used for this purpose, this is a method of analysis that seeks to describe relevant aspects of a specific field of study, in which theory emerges from the data. (Juliet M. Corbin & Anselm L. Strauss, 2008). The analysis approach used in this study was open code, which corresponds to the inductive process of breaking down data into different units of meaning. This involves transcribing interviews and then analyzing fragments to identify key words or phrases (data unit) linking interviewee narrative to the study phenomena. This type of coding implies an emergence of multiple categories, their theoretical saturation and a deeper data analysis. After constant comparison, analysis and coding, total saturation is achieved when all data are adapted to emerging categories (Spiegelberg, 1994). Interviews were carried out by the three coders (Principal investigator and two child psychiatry fellows) through successive meetings. This had the purpose of triangulating the analyses and reaching an intersubjective agreement regarding categories, concepts, and any properties developed (Flick, 2004). During this process an external advisor was consulted regarding emerging results to facilitate findings. The ATLAS.TI v7 software was used to this purpose.

RESULTS

Recruitment feasibility

Participants were enrolled from August 2017 to February 2019, data collection was completed in April 2019. Recruitment and study flow-diagram is presented in **Figure 4**. During enrollment period, 51 children were admitted to the inpatient unit, 36 of whom had a primary caregiver who visited regularly during intake, with an eligibility rate of 70.58%. Main exclusion criteria were not having a primary caregiver during their stay, 13 of whom were institutionalized children, with minimal, or no contact with any of their attachment figures. A further two children were in transition to an institution, yet the mother of one of these children refused any kind of family intervention, while the grandparent of the second child suffered severe cognitive impairment. Recruitment rate was 83.33%, 36 eligible cares were invited, six declined, four of whom were single working mothers with scheduling conflicts and two who were not willing to be involved in a research study.

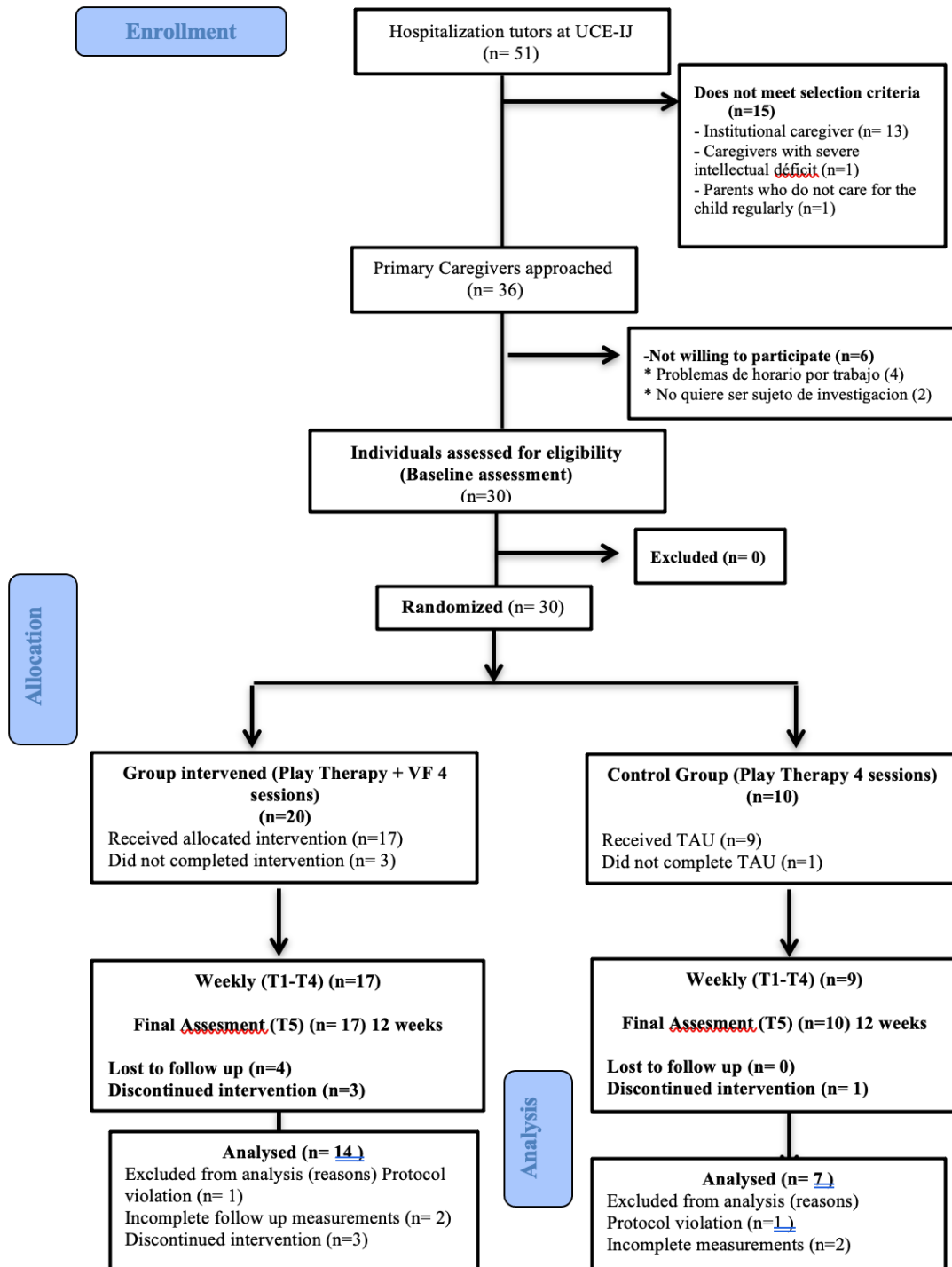


Figure 4: Study Flowchart

Delivery Feasibility

During the 18-month research period, weekly play therapy and VIT sessions were held, bar a three-week hiatus. Both workshops were co-facilitated by two therapists, although sometimes only one therapist was present. A total of 4 therapist delivered the intervention, two were available for the initial ten months of the research period and the other two were available for the remaining time, all therapists were trained and supervised by certified VIT supervisors. While VIT was designed to be conducted in a group setting, it was common, for at least one session with each caregiver, to occur individually, because there was no other caregiver available at that time. Individual sessions were used to explore caregiver childhood, and to what extent she feels that the way she was raised as a child may influence her experience as a mother.

The compliance-to-intervention rate was 85% in the VIT group (17 out of 20 caregivers) and 90% in the control group (9 out of 10 caregivers). Three caregivers dropped out of the VIT workshop, upset with the inpatient unit team after their decision to file a “child abuse report”, so mothers refused any further intervention. One control group caregiver did not finish play therapy because the daughter refused to see the mother for an extended period.

Neither the caregiver nor the child reported adverse effects during play and VIT therapies. No caregiver reported any problems with VIT therapists.

Feasibility of data collection and outcome measures

All participants completed the entry evaluation, 26 completed evaluation at the end of intervention (86.66%), and 27 completed the 12-week follow up evaluation (90%). **Table 5** presents means, standard deviations, change scores from baseline for intent-to-treat group. All questionnaires were checked for completion upon delivery, so that staff could encourage participants to complete them in real time and answer any questions they may have. There was a 100% completion rate for baseline assessment, the overall completion rate was 93.80%. The completion rate for outcome measures for participants finishing the trial (n=27) was 97%.

Table 5: Baseline and change data for intent-to-treat

	Intervention Group (TAU + PT + VIT)			Control Group (TAU + PT)		
	Baseline mean(SD) n=20	Mean Change (SD) BL to PT n=17	Mean change (SD) BL to Follow up n=16	Baseline mean (SD) n=10	Mean Change (SD) BL to PT n=9	Mean change (SD) BL to Follow up n=9
PRF	2.45 (1.19)	0 (1.62)	0.19 (1.67)	3.6 (1.51)	-0.11 (1.05)	-0.67 (.29)*
GHQ-12	19 (8)	-11.05 (8.14)*	-5.93 (8.59)	22.1 (6.38)	-9.33 (9.42)	-11.11 (6.07)*
SDQ	23.7 (8.68)	-4.88 (5.85)*	-2.25 (5.11)	25.2(8.31)	-4.67 (4.3)*	-6.78 (6.55)
SDQext	12.4 (5.79)	-3.35 (3.2)*	-.88 (3.72)	13.1 (6.42)	-1.56 (3.68)	-9.22 (4.58)*
SDQ int	11.3 (4.57)	-1.53 (4.89)	-1.38 (3.34)	12.1 (3.7)	-9.89 (3.37)	-3.44 (3.64)*
CGAS	39.85 (15.22)	21.06 (18.32)**	17.83 (19.42)**	44.8 (7.58)	16 (11.7)* ^b	14 (19.44)*

TAU Treatment as usual PT Play Therapy VIT Video Intervention Therapy PRF Parental Reflective Function, GHQ-12 General Health Questionnaire-12, SDQ Strengths and Difficulties Questionnaire, ext Externalizing, int internalizing, CGAS Children's Global Assessment Scale, SD standard deviation PT post-treatment, BL baseline,

^a n=18; ^b n=10* p values < .05

Participant characteristics

Table 6 and **Table 7** show demographic characteristics and baseline evaluations for the 30 participants included in this trial.

Change in outcomes

The following are results for primary and secondary outcomes for the 21 analyzed participants (Figure 1). These results are shown in **Table 8**.

Primary outcome:

Mean PRF score for the VIT group (Group 1) increases throughout each measurement, increasing by 0.07 (SD 1.77) from baseline to post treatment and 0.14 (SD 1.23). to the 12 weeks follow up measurement), While the control group (Group 2) shows a decrease in participants' means throughout each evaluation, falling by 0.29 (SD 0.76) from baseline to post treatment and 0.57 (SD 0.79) to 12 weeks follow up measurement. When comparing groups, the mean difference (MD) between the change score in Group 1 and 2 at post treatment evaluation shows that control group obtained higher MD than intervention group (mean difference = 2.90, [CI] = -1.45,.88), with a small between group effect size (ES) of 0.12. This difference was reversed at follow up in favor of the intervention group (MD = 0.48, [CI] = -.61,1.57) with a between group ES amounting to 0.23.

Individual differences in RFS change scores for each group in post intervention and follow up can be seen in **Figure 5**. There are different individual trajectories in each group, in the control group a more homogeneous behavior is observed, where variations do not exceed 1 point between one measurement and another, also the majority (6 out of 7) maintained or decreased their PRF after intervention. A greater variability can be seen in the VIT group both within and between participants.

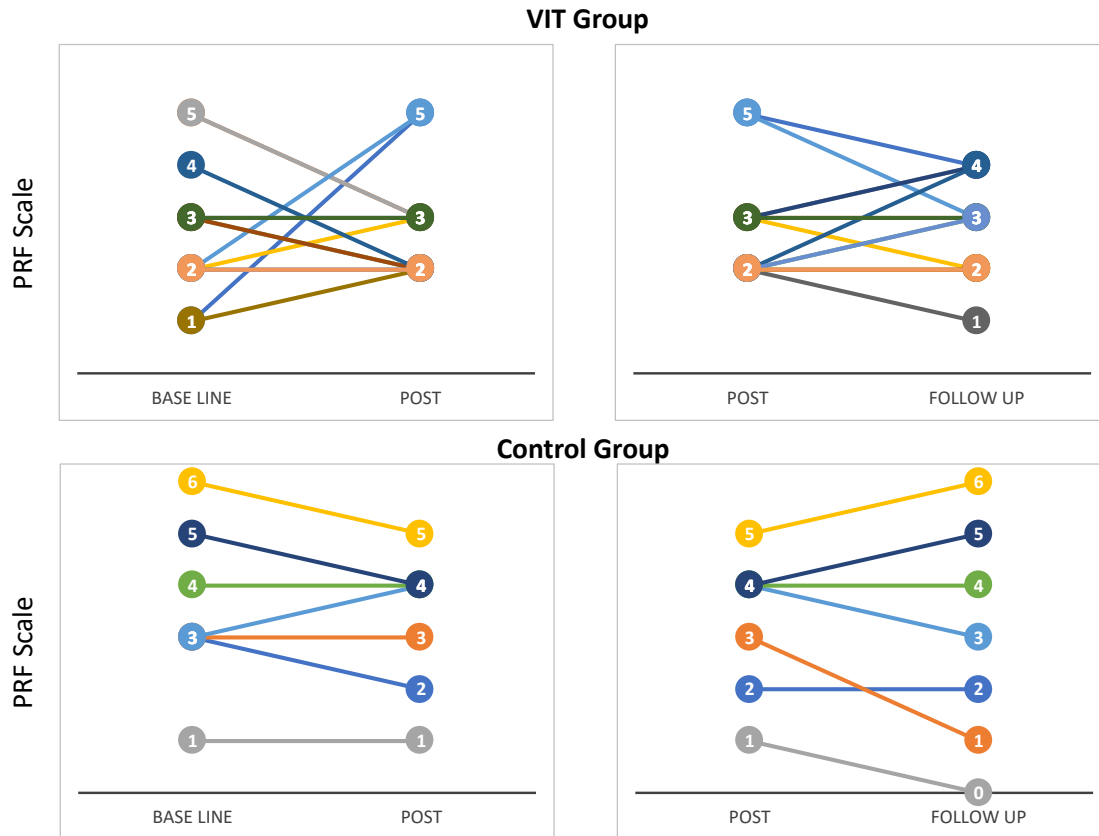


Figure 5: RFS change scores for each group

Table 6: Caregivers characteristics

		Intervention Group (n=20)	Control Group (n=10)
Relation to patient			
	Mother	15	6
	Stepmother	1	0
	Grand mother	3	3
	Adoptive mother	1	1
Age, mean (range)		43.7 (29-64)	51.2 (32-81)
Years of education, mean (range)		10.4 (4-19)	12.1 (4-17)
Employment Status			
	Full time/part time	11	3
	Unemployed	7	4
	Retired	0	1
	Homemaker	2	2
Health insurance	Public exclusive	10	5
	Public non-exclusive	10	5
	Private	-	-
Marital status			
	Married/living with partner	9	6
	Divorced	8	1
	Single	3	1
	Widowed	0	2
Number of siblings, mean (range)		1.90 (0-5)	1.70 (0-6)
Psychiatrist diagnosis*			
	None	10	5
	Major depression	5	4
	Intellectual deficit	1	0
	Bipolar disorder	1	0
	Personality disorder	3	1
Current Psychiatry treatment		4	1

*Caregivers report or from records (clinical formal evaluation was not performed)

Table 7: Child characteristics

		Intervention Group (n=20)	Control Group (n=10)
Sex (female)		10	2
Education			
	Private	3	4
	Public	8	3
	Free exams system	1	0
	Hospital school	2	2
	Special school	6	1
Age, mean		12.3	12.6
	7-10	3	1
	11-13	11	5
	14-16	6	4
Somatic chronic disease		8	0
Cause of admission	Aggression toward others	13	6
	Suicidal ideation	0	1
	Suicide attempt	4	2
	Self-harm	1	1
	Psychomotor agitation	2	0
Days of hospital stay, mean		57.4	75.2
	1 month	3	1
	3 months	15	6
	6 months	2	2
	more than 6 months	0	1
Number of psychotropic drugs, mean		3.10	3.20
	1	1	0
	2	6	3
	3	5	3
	4 or more	8	4
Previous therapy	Individual Psychotherapy	6	5
	Family therapy	3	0
	Occupational therapy	4	3
Maltreatment	Physical	5	2
	Neglect	7	7
	Emotional	9	2
	Sexual abuse	5	2
	Bullying	5	3
	More than one experience of maltreatment	9	5

Table 8: Primary and secondary outcomes

Outcome	Group	Change scores and Between group effect sizes (a)													
		Baseline		Post treatment		Follow up		Baseline – Post treatment				Baseline - Follow up			
		\bar{x}	SD	\bar{x}	SD	\bar{x}	SD	\bar{x}	SD	MD [CI]	f	\bar{x}	SD	MD [CI]	f
PRF	1	2.71	1.27	2.79	1.05	2.86	0.95	.07	1.77	.29	0.12	.14	1.23	.48	0.23
	2	3.57	1.62	3.29	1.38	3.00	2.16	-.29	.76	[-1.45, 0.88]		-.57	.79	[-0.61, 1.57]	
GHQ-12	1	18.71	7.41	8.79	6.38	11.00	6.70	-9.93	6.91	3.75	0.26	-7.71	7.12	.34	0.03
	2	23.86	5.27	14.00	8.27	13.86	6.96	-9.86	10.78	[-10.96, 3.46]		10	6.11	[-6.65, 5.99]	
SDQ	1	21.57	8.76	16.86	8.12	19.50	7.31	-4.71	5.80	1.04	0.10	-2.07	5.28	3.21	0.33
	2	24.43	10.06	20.00	8.74	18.14	8.34	-4.42	4.50	[-5.94, 3.86]		-6.29	6.78	[-1.65, 8.07]	
SDQ ext	1	10.86	5.92	7.50	4.33	10.21	4.10	-3.36	3.54	2.49	0.39	-.64	4.69	1.47	0.25
	2	11.86	7.38	10.71	7.85	9.29	5.35	-1.14	3.98	[-5.74, 0.76]		-2.57	3.89	[-1.46, 4.40]	
SDQ int	1	10.71	4.48	9.36	4.16	9.29	4.27	-2	3.79	0.57	0.08	-1.43	3.50	1.49	0.23
	2	12.57	4.31	10.57	2.37	8.86	3.39	-1.35	4.7	[-3.10, 2.86]		-3.71	3.90	[-1.67, 4.66]	

PRF Parental Reflective Function, GHQ-12 General Health Questionnaire-12, SDQ Strengths and Difficulties Questionnaire, ext Externalizing, int internalizing, SD standard deviation, Group 1 intervention Group; 2 Control group, MD Mean difference (a)= Baseline was used as a covariate to be controlled through ANCOVA analysis

Secondary outcomes:

Caregiver outcome

Parental well-being improved in both groups during the trial. A reduction in the GHQ -12 score of 9.93 is seen the VIT group at post intervention, this difference was smaller at the follow up (-7.71) when comparing with the baseline. The control group showed similar changes with a mean change score of 9.86 at post treatment and 10 point at follow up. Comparison of MD between groups, after controlling for baseline, shows that VIT group had a higher reduction (MD = 3.75, IC = [-10.96, 3.46] with a small to medium ES (f = 0.26). In the follow up, again the VIT group shows a lower MD when comparing to control group (MD= 0.34, [-6.65, 5.99]) with a small ES (f = 0.03).

Child outcomes

As seen in Table 4, in both groups all SDQ scales shows a decrease in their means at post-treatment evaluation. Mean change score for VIT group were SDQ-total = -4.71, SDQ-ext = -3.36, SDQ-int = -1.35, while the control group shows similar scores (SDQ-total = -4.42, SDQ-ext = -1.15, SDQ-int = -2). The intervention group showed higher symptomatology scores on comparing means between groups at the post-treatment evaluation, when controlling for baseline. A small effect size is observed in SDQ-total (MD = 1.04, f = 0.10), a medium-high effect size in SDQ-ext (MD = 2.49, f = 0.39) and a small effect size in SDQ-int (MD = 0.57, f = 0.08). In the follow-up, when comparing means for both groups, the intervention group

showed lower symptomatology scores than the control group in all SDQ scales, with a medium effect size in both SDQ-total ($MD = 3.21$, $f = 0.33$) and in the SDQ-ext ($MD = 1.47$, $f = 0.25$), while in the SDQ-int, the ES was small-medium ($MD = 1.49$ $f = 0.23$).

Qualitative outcomes

Participant semi-structured interviews.

Ten of the 17 participants who completed the intervention agreed to be interviewed. They were six mothers, two stepmothers and two grandmothers. There was no financial compensation for participating in this interview. Interviews were arranged when the child had an appointment at the hospital, so caregivers who did not continue treatment in the outpatient clinic reported more difficulties in agreeing to the interview.

Two main categories emerge from the analysis: ‘Workshop Perception’ and ‘Perceived Benefits’. These categories had several subcategories as seen from the caregiver’s narrative. The foundations of these categories are described alongside verbatim quotes illustrating them. Participants are identified in each quote using codes for interview number, relationship and age.

1. Workshop perceptions: What they thought about their participation

- a) Motivation to attend: The caregivers report that they accept participation in the trial because they felt it as an opportunity to received help and because it was a space for dialogue. Some of them also believed the intervention was part of the inpatient treatment.

“Because I thought: ‘this is the opportunity to help my son’. He had been going to the psychiatrist for a long time, but he did not have a therapist or anything. Then I thought this could be the opportunity; thanks to God it was like that!”. Interview number 2, mother, 36 years old.

- b) Difficulties seen in workshop participation: several caregivers mention various problems in participating, in both interventions (play therapy and VIT). Mentioning aspects such as commuting distances, plus time and money constraints. Two of them failed to understand workshop purpose. Regarding workshop ambience, they

mentioned that during Play Therapy, if there were any kind of interruptions or when other children were around, the noise became upsetting, and it was difficult to focus in playing with their child or also they mention being uncomfortable with being filmed. They also mention that when their child was upset or restless, it became difficult to engage the child in play therapy.

“Then this other mother was there, and I was there with Camilo, then the mother was like, very loud and played with her child, then I did not like that, because I could not concentrate, I was with Camilo and I tried to get into the head of Camilo, but having to work over this mother, I couldn't do it, but it was the only time I got complicated”. Interview n°1, mother, 30 years old.

- c) Positive workshop references: All those interviewed mentioned positive aspects of the workshop: they liked the number of sessions, the group setting and the video-feedback. The latter because they had the opportunity to see themselves interacting with their child, to observe behaviors that are not normally noticed in daily life, particularly regarding positive aspects on mother and child behavior. Video observation also allowed them to become aware of any improvements seen during the process.
- d) Concerning therapists, carers said that they felt listened to, and that they were warm and flexible, providing sound advice.

“Obviously we don't see oneself, I mean, one doesn't see the way one acts and cannot know that one is behaving incorrectly. But if one sees oneself in the film, then we do realize it, and it is amazing! One goes through life, strong and straight... and without the video saying, “look, this is you” one cannot reflect, one cannot realize that one is doing something badly. The film made me realize that something was wrong.”. Interview n°3, stepmother, 58 years old.

- e) Suggestions for change: Some of them said they would prefer more VIT sessions, include it in the outpatient setting and incorporating the child and/or other family members, such as either the father or mother, or both (many caregivers were grandmothers). Regarding Play Therapy carers prefer interacting with their child in a quiet and private space and to involve more child unit staff members. In relation to the trial, they request greater depth when explaining the rationale behind the instruments,

specifically FMSS, because they found it difficult to understand why it was necessary to answer the same questions every week.

2. Perceived benefits

- a. In general, carers reported that VIT was an effective help, which supported them during their child's hospitalization. Support came both from therapists as well as from other parents during group sessions, as they felt understood by them. These participants helped them to see aspects in the videos that they could not see by themselves, including positive interactions between them and the child, and this proved to be, in a crisis setting, was both comforting and encouraging.

“They help me to find the right words to say in certain situations, I don't know..., for example how to react to Esteban's anger, because when he is angry the situation is not exactly rosy. When he was enraged, he could kick anybody passing in front of him, he could hit the wall with his fists. In this, they help me a lot, how to contain him, how to handle him”

Interview 7, mother, 29 years old.

- b. Identify parenting problems: Caregivers mention that, through looking at their interactions with their child in the video, they identified certain situations at home where they could act or feel different about their children. All situations mentioned by them were organized in two main themes, difficulties in expressing emotions and difficulties in setting rules and boundaries.
 - i. Emotional expression: They reported that sometimes they could overreact vis-à-vis the child's behavior, and get angry very easily, not paying attention to the child's feelings, not expressing love to the child, describing the child in light of their negative aspects, and not sharing with them any play spaces in the home.

“In the past, I couldn't control myself... For example, I used to shout, I could yell at him and on occasions I could hit him. Then I would turn around, my husband would go to calm Juan

and I would go to cry in my room, full of remorse... because I know I should not hit him. But not now, ...and I say to myself, "My Goodness, I have changed!"". I2, mother, 36yo.

- ii. Setting rules and boundaries: Being authoritarian, or to give them anything they want, not being clear in rules (or contradicting the norms), to allow the extended family taking decisions that should be taken by her, not intervening when another adult in the home ill-treats the child and failing to set boundaries due to fears of how the child might react.

"Because, for example, if he wanted an ice cream, I would give him the ice cream. If he wanted me to stand on my head, I would stand on my head, if he wanted to go goodness knows where, I would take him there. The whole family behaved like that, his daddy, the older sisters; whatever he fancied, it was given to him, to avoid him throwing a tantrum, to avoid him breaking things" I5, mother, 50 years old.

- c. New strategies: Together with becoming aware of their parenting difficulties, they start to practice new driving behaviors

- i. Communication: Acknowledge the problem and talk about it, without disqualifications. Providing positive reward, taking into account the child's opinions, identifying any preferences, finding out common interests, giving explanations about what the child does not understand, and sharing with him what the adult thinks and feels.

"Now I sit with her, or we go for a walk. 'D, what is the matter? I feel there is something wrong, I know you' ... 'I don't think it is nothing ...' "I feel something is happening, ...tell me, perhaps I could help you, let's talk" I3, stepmother, 58 years old.

- ii. Related to affections and emotions: Keeping calm before reacting. Imagine what the child might be feeling, finding ways to calm the child (first, by calming herself, then distracting them and connecting with their emotions), avoiding escalating aggressions, pondering and repairing negative reactions against the child.

“I say to him, ‘. Jorge, I am fed up with you. Why don’t you go to hospital, I am tired with you, obey me...’ and then, I reminded myself! And I thought ‘No, something might be happening to him’. So, I said to him, ‘forgive me that I shouted at you, sit down, and tell me, what is the matter?’ He said, Mum, I wanted to do this or that, and I said, ‘We’ll do it later, on our return; I have to go out and I cannot leave you alone, we will go out, we will come back and then you will do it’. He replied, ‘Okay’. I realized then that, before, he would have shouted, ‘I’ll do nothing at all!’ and he would have been distressed.”. I2, mother, 36 years old.

- iii. Related to rules and boundaries: Defining the rules and respecting them, being flexible vis-à-vis child’s needs, setting boundaries through dialogue, keeping the child apart from conflictive situations, avoiding children’s involvement in adults’ problems, intervening in case of verbal aggression to the child by other adults.

“I am not any longer the way I used to be. I was permissive, I used to accept anything, I kept quiet - Not any longer; I say whatever I need to say, I do whatever I need to do.” I8, grandmother, 59 years old.

- d. Changes in the way the child is perceived: They feel that they understand better the child’s problem, they are able to acknowledge positive changes, they can put themselves in the child’s place when the child is feeling poorly, when the child is insistent in certain demands or behaves inadequately. They manage to read better the child’s body language, thus being able to identify better their different emotional states.

“It happened that I did not know how to contain her, I didn’t realize that she did all that so as to be taken into account ... now it’s better because I have a psychologist, the lady doctors, the play time. Thus, I spend more time with her, I ask her questions about her, ...if she feels good or poorly...” I9, stepmother, 61 years old.

- e. Family repercussions: Carers reported that they could transmit to the rest of the family what they had learned in the workshop, they could observe the positive changes occurring in the family, such as showing more respect for each other,

expressing better their loving feelings and finding more spaces to share. Some mothers reported that they recovered their authority within the family.

“My husband also learned how to control himself, because before he would shout in anger. Now with just one look, ‘go talk to him’, goes upstairs and then he comes down already calmed” I2, mom, 36 years old.

- f. Persistence of the changes: Carers gave concrete examples about their ability to transfer what they had learned in the workshop, whilst the child was hospitalized, to their daily life at home after being discharged.

“Last night for example, during Nina’s homework time, I realized that something was wrong with her [...] because of her facial expression, her gaze... I understood and then I talked with her.” I8, grandmother, 59 years old.

Inpatient-unit team interviews

These interviews contribute to a better understanding of delivery feasibility (therapist interviews) and implementation feasibility at an inpatient child psychiatry unit (team unit interviews), the persons interviewed are described in **Table 9**.

Table 9: Clinical team interviews description

Profession	Gender	Age	Role at the unit	Experience (years)	Child mental health experience (years)
Psychiatrist	female	38	VIT therapist and psychiatry	12	10
Psychology	female	38	VIT therapist and psychology	13	13
Psychology	female	28	VIT therapist and psychology	3	2
Psychology	female	26	VIT therapist	3	2
Psychiatrist	male	63	Chief psychiatry	37	29
Psychiatrist	male	38	Psychiatry	14	7
Nurse	female	29	Chief nurse	4	4
Paramedic	male	28	Paramedic	6	5

- Therapists' interviews

Four therapists were interviewed, two of them were classified as senior, because they had greater clinical experience and were qualified VIT teachers. The other two were junior therapists as they were under training and with supervised VIT by senior therapists. The open code used in these interviews allowed for the emergence of these two categories.

1. Motivation and perceived benefits: For therapists, participating in these interventions gave them the opportunity to learn a new technique; by learning about VIT they realized it was a useful tool for going beyond diagnosis and to have a more sensitive understanding of the child, and build a better knowledge of the carer's upbringing and the way their life history may have affected their relationship with their son. There was also a favorable impact at work with the extended team as every week the processes of each dyad were reported in the team meeting. Besides, paramedics also participated in the games workshop. The two junior therapists valued the opportunity of gaining clinical experience and senior ones felt challenged for bringing into practice their creativity and flexibility.

"Compared with what I have done before, this was a completely different experience. In general, one approaches parents with certain ideas about how they should change or deal with children. There are only a few opportunities to work together with parents, examining our own thoughts and, progressively, understand parents' anxieties, expectations... which they might transfer to their children. At the same time, understanding what obstacles there might be to visualize the child's need. Previously, with my university background, I used to think, 'blimey! why this dad is not doing this or that'. And one also understands the child's vulnerabilities from the point of view of certain interactions and not necessarily as something that is intrinsic to them." Young therapist.

2. Conditions necessary to practice VIT: The therapists reported.
3. (a) the need to program the necessary time (extra time is required to analyze videos and prepare the workshop; they concluded that this required 30 to 60 minutes of work per week, according to the number of carers). (b) Technical supervision, which can be scheduled for according to the professionals' prior training and knowledge about VIT,

young therapists also had the requirement of accepting weekly supervised sessions, during which the videos were analyzed by the whole team. This resulted in an extra hour per week to prepare the workshop.

4. (c) Technical requirements such as internet access, cameras or cell phones and play materials.
5. (d) Collaboration from the team members in preparing the workshop room, to avoid interruptions to the play process (with tasks such as blood pressure checking, administering medicines, amongst others), and, most importantly, be available in case the primary care giver is not present for the play workshop or any other contingency (for example in case of child agitation or aggression between peers).

“These were some situations that occurred during the workshop. The children were playing, as part of the therapy process, and suddenly it was mealtime, and the assistant workers would arrive with the food. From the point of view of the workers, ancillary, nursing or paramedic staff, this was never an interruption, but from the therapeutic point of view, there was a clear interruption of a process.” Senior therapist.

- Key stakeholders

The ward nurse, the play workshop paramedic and two psychiatrists were interviewed. Responses were classified in two groups, according to the generated codes: 1) Repercussions regarding the running of the ward, and 2) Difficulties and suggestions regarding implementation.

- 1) Regarding the ward running: the group described some benefits of VIT including adding to in-patient services, a new psychotherapeutic intervention, giving paramedics an opportunity to participate with the children in a therapeutic activity, delivering relevant clinical information, and, finally, being part of valuable teamwork. Regarding the research itself, both psychiatrists considered the above as contributing to the operation and dissemination of the unit's work. There were concerns concerning the control group, but the fact that everybody participated in the play workshop meant that all children had the same daily routine. Some parents requested attending the VIT workshop, which was allowed once the study had finished.

“In my opinion, the greater change occurred in parents; not so much in the unit - the impact was stronger for parents; they were a bit more aware... daddies appeared to be more involved during the child’s hospitalization, it seemed that their commitment with their children was different” Paramedic.

- 2) Regarding implementation difficulties, they mentioned that prior to the study start there were problems in the working atmosphere, not everybody in the team knew or fully understood study objectives; but they gradually did so as the research progressed, and they involved themselves more and more after witnessing the changes seen in children and their families. They reported that not all the nurses or paramedic showed the same degree of commitment, some collaborated more than others. They are of the opinion that this intervention would be more successful in outpatients, as they are more stable, clinically.

“A brief training is necessary [in all cases], as the staff is not always the same, there are temporary staff – they may try to do the utmost, but sometimes they don’t have the knowledge or the understanding about what to do or not to do. We have had cases where the mother is playing with the child, and then the paramedic instead of standing by, he/she intervenes in the play, and of course, this alters the dynamics” Chief nurse.

DISCUSSION

The present study sought to evaluate the feasibility and acceptability of VIT intervention to enhance PRF in primary caregivers of children in an inpatient psychiatric unit. Quantitative and qualitative methods were used to determine plausibility of a progression to a full-scale multi-center RCT.

Eligibility and recruitment rate were 70.6% and 83.3% respectively. This is similar or better to other RCTs using VF to improve parenting (Høivik et al., 2015; Poslawsky et al., 2015). The former compares favorably with other trials delivered in child inpatient units, for example, it fared better than the Rimehaug et al study of 2019 (Rimehaug, 2019), where recruitment was 67.5% and eligibility was not reported, yet fared worse than Ise et al trial (2015) (Ise et al., 2015) where a 91% eligibility and 93% recruitment was obtained. A third of the children admitted to the unit were institutionalized, which became the main reason for not being

eligible. Refusal to participate in the study was attributed mainly to difficulties in attending due conflicting work schedules. Only a few working parents had paid work leave. Hence, we introduced flexibility as the study progressed, scheduling VIT sessions to facilitate participation and adherence.

Instrument Completion rate for the set of instruments was high, with minimum instrument loss, possibly because they were applied and checked for completion at every assessment point. In the qualitative interviews, it was observed that some caregivers had difficulties in understanding the relevance of answering the same questionnaires and the FMSS at the end of each session, which could affect the quality and richness of their responses.

There were no issues seen in randomization although four caregivers in the control group said they would have preferred to be in the VIT group, and they were offered to participate in the video groups after completing the study. One case was excluded from the analysis due to having received a PRF-based intervention which analyzed what was observed during play therapy.

Completion rate was high in both groups, although lower in the intervention group (85% v/s 90%). The only reason for dropping out from VIT was when the professional had to file a “child abuse report”. As can be seen in the results, the frequency abuse and neglect is high in hospitalized children, so it would be interesting in the future to identify those caregivers at risk of "abuse or neglect". In these latter cases it is possible that a protocol modification be required; namely, more sessions, with individual sessions at the beginning aimed at working on motivation and rapport. In those cases where a “child abuse report” should be filed, psychological support or treatment for the adult ought to be included, since even if the child is referred to an institution, he or she will continue to be in contact with their attachment figures. There are some attachment-based interventions for multi risk families that have achieved successful outcomes with ten session (Berlin et al., 2019) and even six sessions (Negrão et al., 2014) which include home visit sessions. Completion rates are improved when individual sessions in flexible time or at home visits are included (H. Steele & Steele, 2018). The trial included several random individual sessions, yet not part of our protocol.

The aim of our VIT program is to be part of a larger treatment, each dyad having different therapeutic goals in terms of needs, resources and phase of their ambulatory treatment. Caregivers with disorganized attachment or with a history of trauma will presumably need a longer intervention.

Study Acceptability

Qualitative interviews showed that caregivers value the empathic and sensitive attitude seen in therapists and the group support achieved. Caregivers also differentiate what they achieved from VIT vis a vis other intervention. Participants and therapists valued the group sessions for their emotional containment of the other participants and reflections from other caregivers regarding what is seen on the videos made it easier for them to relate, understand and accept.

The whole group looked for strengths of each other and themselves during the interaction seen in the videos with a non-judgmental attitude, something actively sought by therapists. The shared stories seemed to become a community value, having a unique worth for families who have experienced trauma (Denborough, 2008). The positive evaluation of video use was clear in several instances, seeing themselves and how they evolve session after session. Moreover, the power of video is shown by seeing children in a different light, glossing over symptoms and behavior problems to observe constructive behaviors, often unexpected in them, such as collaboration, positive emotionality and respect. The subjective experience of interviewees referred to different benefits of VIT, such as reflecting on parenting problems (no longer focusing on the children's problems), developing new behavioral management and emotional regulation strategies that they put into practice when the child was at home. Overall, it was possible to access the subjective experience of the caregivers who participated in this intervention. They saw this space as an opportunity for obtaining knowledge about themselves and their children, valuing understanding and acceptance, acquiring new skills for parenting and feeling able to put them into practice. The mere fact that some mothers are able to feel "more capable" justifies these brief and tailored interventions. The work of Berthelot et al (Berthelot et al., 2015, 2019) shows a strong concordance between mother and child insecure and disorganized attachments, indicating an intergenerational transmission of attachment in parents with childhood histories of abuse and neglect. They emphasize in the importance of

trauma specific mentalization, suggesting that is not the experience of trauma, but the absence of mentalizing regarding trauma that underlies this transmission (Berthelot et al., 2019).

Key-stakeholders' interviews highlight the relevance of having support from the head psychiatrist when conducting the trial, because there were apprehensions before the trial start, such as changes in unit function and excess workload. Towards the end of the study the nurse, paramedic and staff psychiatrist valued the intervention in its contribution to their clinical work, and in the acquisition of deeper knowledge and understanding about dyadic dynamic, while parents were more involved in their child hospitalization. Although the study could have generated a greater workload for the staff members, this was not pointed out by them at the end. For future studies it will be important to improve the induction process for staff, inform the objectives, the theoretical foundations and development of the intervention. It is expected that this will generate greater involvement from the rest of the team members and effectively incorporate newcomers. This then becomes an opportunity to reinforce training in child mental health for nursing staff.

From the interviews with the therapists, it appears that supervision is always required, but the frequency varies according to therapists' experience. Young therapists were required to have weekly supervision to discuss and prepare the workshop, this needs to be considered in a larger study, including theoretical training in the technique plus one to two hours of group supervision per week.

Change in outcomes

Basal levels in PRF were low, lower than 4 means a failure in mentalizing their children, that pattern is common in persons with borderline personality disorders (Bateman & Fonagy, 2012), but also in other disorders such as depression, eating disorders and obsessive compulsive disorders among others (Katznelson, 2014).

When comparing groups at the end of intervention, the control group shows higher levels of PRF than the intervention group, but at follow up that difference was reversed, both with a small ES. It was expected, to a certain extent, that by the end of the intervention caregivers would have shown a decrease in PRF, since group VIT was a source of emotional support for them, as expressed in qualitative interviews

Several caregivers mention the desire for a longer intervention, that continued on an outpatient basis. Follow up was made 12 weeks after recruitment, most of the children were either discharged by then, or at least had some home leave permits. It is anticipated when children return home, that parental stress will increase, generating temporary decreases in parental and child emotional regulation until they have re-adapted to functioning at home. It seems, therefore, that the effect of VIT continues after returning home. The parents in the VIT group became aware of different problems linked to upbringing, as can be seen in the qualitative interviews, so it is possible to suggest that it is at discharge when they display what they have learned during the intervention. PRF is a meta-cognitive skill susceptible to modification with therapy, it has been demonstrated that people with lower levels will need prolonged therapy to modify their functioning (Fischer-Kern et al., 2015). Although the reflective functioning scale (RFS) ranges from -1 to 9, it is an ordinal scale, in clinical terms a difference of one point accounts for different clinical situations, especially if one moves from non-mentalizing states (score 3 or less) to mentalizing states (score 4 or more) (Fonagy et al., 1998; Sled et al., 2020).

Regarding secondary outcomes, the results in SDQ scores deserve special mention. In both groups there is a decrease in SDQ scores and improvement in functioning according to C-GAS. Similar to what was observed with PRF, when comparing groups at the end of intervention the control groups show a greater decrease in the three scales, with small ES for SDQ total and internalizing, and medium-high for the externalizing scale, but at the follow up those results were inversed in the three scales, with medium ES. These results are clinically relevant, since the intervention is focused on the parents, so a potential effect at the child level is promising. It will be useful to evaluate the mediation of PRF in these changes, since SDQ was answered by parents. It is therefore possible, on the one hand, that VIT parents were able to reflect in greater depth on their children's behaviors and emotions, evaluating as less disruptive any externalizing behavior, as well being more aware of unseen internalized problems. On the other hand, it is possible for caregivers to respond more sensitively to the child's needs, with a better capacity for co-regulation between them. In this way, an enriched bond between caregivers and children can allow this relationship to function as the necessary

scaffolding for children to improve their symptoms. Based on this, for future studies it will be important to include tools that evaluate the children's perspective and attachment.

Strengths and limitations

The study combines quantitative and qualitative methodologies, this is recommended for feasibility studies and for research involving psychotherapeutic interventions. Caregiver and child variables were included, such as PRF measurement, a highly relevant parental competence that has been underreported in studies using video feedback (O'Hara et al., 2019). Several actors were interviewed in depth, which allowed us to evaluate acceptability and feasibility from different perspectives. The qualitative and quantitative results are related allowing to understand new aspects, generate hypotheses and recommendations when preparing a larger scale study aimed at evaluating intervention effectiveness. The study showed the utility and clinical value of VIT as a tool for caregivers' intervention in children having severe psychiatric disorders. The reduced number of sessions allows for adjusting to restricted public health system resources. The supervision and training of the therapists allowed a rapid uptake of VIT techniques.

One shortcoming of the study was the omission of qualitative interviews with the caregivers who participated in the control group. Another limitation is that several parents reported that they would have appreciated to be part of the VIT group, perhaps in a larger study the control group should participate in another type of parent meeting. The change in the main outcome was less than expected, for a future study it is advisable to change the main outcome, possibly to SDQ, where greater ES were observed. It is also possible that more sessions will be required. Repeated measurements of the main outcome were made in order to do a larger study with a multilevel design, but the caregivers did not evaluate well having to repeat the FMSS, this could affect the quality of the instrument, so it is not recommended to perform FMSS every week. A future study could include direct assessment of recorded play therapy, which can be done in each session, to evaluate the behavior and emotional regulation of each, as well as the quality of the dyadic interaction. Finally, in a future study it will be important to perform a formal assessment of mental health problems in caregivers and early trauma experiences (Ensink et al., 2014).

Conclusion

In summary, the current study presents the first evaluation of VIT for caregivers in an inpatient child psychiatry unit, the clinical trials were proved feasible to conduct and indicates that it is possible to undertake future multicenter study based on this trial design to evaluate effectiveness of VIT on child and caregiver's health outcomes.

List of abbreviations

PRF: Reflective Parental Functioning, VF: Video Feedback, VIT: Video Intervention Therapy, RCT: Randomized Clinical Trials, FMSS: Five Minute Speech Sample, GHQ General Health Questionnaire, CGAS: Children Global Assessment Scale, SDQ: Strengths and Difficulties Questionnaire.

Declarations

Ethical Approval and Consent to participate

Full ethical approval was obtained from the local Ethics Committee (Comité Ético Científico del Servicio de Salud Valparaíso- San Antonio, ORD 1502, date 8-8-17). The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (1996) and the principles of Good Clinical Practice (such as data storage and administrative functions).

Written informed consent was obtained from participants in the study (adults and children). Participants were free to withdraw from the study at any time without giving a reason and without their care being affected. All the information collected during this trial it is confidential.

Interviews which are transcribed were anonymized at the point of transcription. Any third party involved with transcribing of interviews signed a confidentiality agreement and was fully instructed in how to anonymize transcripts.

Consent for publication

Not applicable.

Availability of supporting data

The datasets used during the current study is available from the corresponding author on a reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

FL conceived the study, set up and managed the trial, collected and analyzed data. MO and RA and HS were involved in managing and advising the project. JM, CC, CS and ML collected and analyzed quantitative data, AA and CH collected and analyzed qualitative data. All authors contributed to the drafting of this paper and approved the final manuscript.

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5. Conclusions and discussion

The rationality for this doctoral dissertation lies in a simple premise: How can we help our children in a psychiatric ward so that they don't have to come back? To this end, a substantial gap in research was addressed namely, how to set up and deliver a novel intervention to improve parenting skills in a hospitalization setting. Family Functioning has been found in several studies to correlate with outcomes of inpatient psychiatry children (Green et al., 2007; Serim Demirgoren et al., 2017; Sourander & Piha, 1998; Timlin et al., 2015). On the other hand, there are several systematic reviews and meta-analyses that demonstrate that “parent-based interventions” are effective in improving child mental health symptoms (such as externalizing problems), parenting behaviors and perceptions, parental mental health and relationship quality (Acri & Hoagwood, 2015; Carr, 2019; Eldridge, Chan, Campbell, Bond, Hopewell, Thabane, Lancaster, O’Cathain, et al., 2016; Leijten et al., 2016; Leitão et al., 2021; Lindstrom Johnson et al., 2018; Patel et al., 2017; Pedersen et al., 2019; Tarver et al., 2019; Tully & Hunt, 2016; Weber et al., 2019). Nevertheless, there remains a lack of evidence regarding family intervention being suitable to be delivered during psychiatry hospitalizations. For children who, after a psychiatric hospitalization, return to their families or have a regular contact with them, it is important to find a safer and nurturing relationship environment with their closest family members, and specially with their attachment figures firstly to overcome hospitalization experience and then to continue towards achieving well-being.

The first article of this dissertation corresponds to profile descriptions for children and families hospitalized in a public psychiatry ward, for whom the intervention was subsequently designed. Fully identifying the target population for this research was a fundamental step to identify some key characteristics that a psychotherapeutic intervention should have for this group, and to estimate the number of possible participants to recruit within the proposed timeframe for the development of this doctoral thesis research.

The second article is the study protocol registration, a recommended step when developing clinical trials, allowing a speedy dissemination of trial designs and rationality, and improved interpretation of study findings, avoiding bias in results and publication (Li et al., 2018)

The last article shows study results, answering thesis objectives. It was demonstrated that an adaptation of an attachment intervention, Video Intervention Therapy (VIT), was feasible to be delivered in a public psychiatric ward in Chile, and caregivers who participated in this intervention felt satisfied with it. These results provide the basis for designing a larger scale study to evaluate VIT effectiveness for parents of children with severe psychiatric pathology.

The results of the pilot RCT on VIT shows that caregivers who were randomized to intervention, compared to controls, at the end of the study had improved in their level of well-being and PRF, in addition stating that their children decrease their externalizing symptoms. All effect sizes were low or medium (see **Table 8:** Primary and secondary outcomes). With the data presented, we can calculate the sample size of the RCT according to the main outcome to be chosen. For a design with a power of 80% and a significance level of 0.05 to estimate the effectiveness in improving PRF (measured with the FMSS and PRFS, $ES = 0.12$) the sample size should be 548 caregivers, unfortunately that sample size is difficult to achieve. If the level of well-being (measured with the GHQ, $ES = 0.26$,) is chosen, the sample size drops to 120 subjects. Finally, if the main outcome is the decrease of externalizing symptoms (SDQ-Ext, $ES = 0.39$) the sample size is 54 subjects. Adding the observed drop-off, there should be 32 subjects (15% more) in the intervention group and 30 (10% more) in the control group. Lastly, if we consider the loss of measurements and other causes for which subjects were excluded from the analyses, a total of 30% more participants should be added to each group, meaning there should be two groups of 36 caregivers. This number seems adequate to fulfill in a larger RCT.

The results in child symptomatology were unexpected. It was predicted that all inpatient treatment children would improve their symptoms in the short term, however caregivers reported that their children showed rapid symptomatic improvement, indicating the potential that this intervention has in limiting the length of stay and prevent re-intakes.

Change in PRF was chosen as a main outcome considering attachment theory and the evidence available today. It has been demonstrated that this parental metacognitive ability is susceptible to be modified in short term and is related to a better emotional regulation of parents and their children, preventing the development of psychopathology (Camoirano, 2017; Ensink, Bégin, et al., 2017; Huang et al., 2020; Sharp & Fonagy, 2008). Parental Mentalizing or Reflective

Functioning refers to caregiver's capacity to reflect on their own mental experiences during interactions with their child and how they could change as a result of these interactions with the passing of time, and also, how those interactions could influence the caregiver's thoughts, feelings, and behaviors toward his or her child (Ensink & Mayes, 2010; Luyten et al., 2017; Slade, 2005). The caregivers in this sample had a marginal yet clinically relevant improvement in their FRP. The entire sample had low levels of FRP at the beginning and during follow up, parents with poor RF characterized by negative and distorted cognitions or representations of reality (Letourneau et al., 2020; Luyten et al., 2017) and by the tendency to make maladaptive and negative attributions about the child behavior. VIT gives a unique opportunity to see and calibrate those distorted representations.

Poor PRF has been found in other samples of parents with severely maltreated children (Ensink et al., 2015), like this sample where all the children had have experience of severe maltreatment and neglect (see **Table 7: Child characteristics**). Child maltreatment is a complex phenomenon where it is common to find a family system with chronic stressors in factors such as parental depression, poverty, addiction, and family violence (Anis et al., 2020; Murphy et al., 2015) and an intergenerational transmission of trauma (Berthelot et al., 2015, 2019), where parents have low sensitivity and responsiveness, with unsupportive and hostile behaviors toward their children (De Falco et al., 2014; H. Steele et al., 2019). This is relevant, because a secure attachment and having parents with good enough PRF have demonstrated to being a protective and resilient factors against child maltreatment and its consequents (Berthelot et al., 2015; Borelli et al., 2019; Ensink et al., 2014). Besides parental mentalizing is a strong predictor (more than parental sensitivity) to secure attachment (Zeegers et al., 2017).

There are different possibilities that can be explored in a future RCT to better address change in FRP, one option is performing a longer intervention, since parents with psychopathology, history of trauma, and with baseline levels of pre-mentalizing FRP may require a longer intervention lasting a minimum of 6 sessions. Another option is to change the way FRP is measured, making it better at measuring short-term changes. The chosen instrument, the FMSS, is a brief instrument that parents answer alone in front of a tape recorder, but it is likely that in these parents, changes in the FRP are better observed in interviews or by measuring

mentalization in interaction with the child, for example through the Reflective Parenting Assessment, implicit when interacting with school-aged children using an adaptation of the Squiggle paradigm developed by Winnicott in 1968 (Ensink, Leroux, et al., 2017). There were no advantages in performing repetitive measurements on PRF, so there is no need for these measurements in full scale trials.

The intervention proposed (see Appendix 1) has the strength of being a flexibly manualized intervention that can be tailored to the needs of each child and caregiver, independent of child diagnosis and caregivers' mental health problems. VIT delivered with play therapy can be easily integrated to any psychotherapeutic approach, meaning that it becomes suitable for learning in short period of time when a therapist has some clinical psychotherapeutic background, and for young therapist the continuous process of seeing videos and supervisions allows them to achieve sufficient skill in delivering this type of intervention in a highly complex population. Delivering VIT in a group format has significant advantages, while it allows working with more caregivers, remaining cost-effective in public health, it also allows for groups, within attachment base interventions, to access support and peer learning opportunities (H. Steele et al., 2019), this were captured by in-depth qualitative interviews with caregivers.

Limitations and future directions

Given the results exposed it wouldn't be advisable to measure adverse child experiences or early trauma in caregivers, because having a sample with a low level of FRP and a high frequency of child maltreatment, it is to be expected that parents experience trauma. Another important limitation was not to evaluate child's mentalization, which would have contributed to better understanding how parental mentalizing correlates with child mentalizing in children with psychopathology. Finally, this study missed the opportunity to evaluate interactions through codification of play videos, this is particularly relevant because the rationality behind improving PRF is to enable parents to better regulate their feelings and behaviors toward their child, in the context of parent-child interactions, especially when children are in distress. This would lead to a better parental sensitivity and responsiveness, something which is clearly seen in the video samples than in the interviews or questionnaires.

In summary, for a future full scale RCT the recommendation is to 1) have the main outcome change to one of child symptomatology, specifically externalizing behaviors, 2) extend parental evaluation to include early trauma experience and mental health status, 3) extend child evaluation to include child mentalizing, 4) modify the way PRF is assessed, 5) include an assessment on relationship changes through video analysis, and 6) Add more VIT sessions for complex issues. Pursuing a full scale RCT is a possible and necessary next step to fulfill expectations in providing a tailored, evidenced based, and cost-effective intervention, for parents or caregivers of children with psychiatric illness in public health settings.

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6. Appendices

Appendix 1: The Intervention: Video Intervention Therapy

VIT is a technique developed by George Downing (G. Downing et al., 2013; George Downing, 2008) and influenced by the research work of observation and microanalysis of videos of mothers and infants (Beebe, 2003; Fivaz-Depeusing & Corboz-Warnery, 1999; Tronick, 2003). VIT is manualized with respect to ways of collecting and watching videos and preparing the feedback for the parents, with accommodation to clinical contexts where time is scarce, and there is urgent need to promptly prepare feedback for caregivers with the objective of promoting changes at a behavioral and representational level, dependent to some extent on the openness of the caregiver with whom the therapist views the video. The type of videos that are recorded, the participants and the setting are flexible. This allows adapting the technique to different contexts and situations in clinical work. The only requirement is to obtain a video of about 5 minutes in length and as far as possible capture the whole body and faces of the people participating in the video.

There are different ways to view and make sense of any video. G. Downing et al., 2013 recommends that an initial “scanning map” should be constructed based on 8 parameters: 1) Emotional connection, 2) Organization of pace, 3) Organization of time 4) Discourse development, 5) Autonomy, 6) Boundaries 7) Negotiation and 8) Collaboration. This "scanning map" of the videos is based on different sources including attachment research, video microanalysis and mainstream development research (George Downing et al., 2013b).

VIT as it is being delivered in the Chilean inpatient service

In addition to the theoretical and clinical approaches underlying VIT, the development of this intervention for caregivers of children hospitalized in psychiatric units integrates the trauma-informed approach, that comprises a key feature of the Group Attachment-Based Intervention or GABI (Murphy et al., 2015), that was developed to serve trauma-burdened parents, at risk of maltreating their young children, in New York City.

Most of the families and children who need psychiatric hospitalization in Chile come from a history of intergenerational trauma, so in order to try to break that pattern it is necessary to adopt a trauma-informed approach. To this end, we first inquire about the child's developmental history, and then follow up with questions concerning the parents and grandparents. This often reveals a multi-generational pattern of physical and sexual abuse, neglect, community violence, political trauma, loss and others, all of which places the child's well-being at great risk. By understanding the life history of the caregivers, we try to form an alliance with them and respond sensitively with their state of consciousness and readiness (or reluctance) to change. Clinicians take care to help caregivers move forward without provoking new feelings of rejection, that trigger memories of past adverse experience. The professional inpatient team expects to sometimes be seen as a threat to the family, especially in the initial diagnostic phase (typically 1-2 weeks).

Family vulnerabilities and the extent of child mistreatment may only be revealed after the diagnostic phase, during the second stabilization phase, as they initially have a guarded approach which then opens up as they see progress in the child's symptoms and professional/parent relationship

In extreme cases, where parental rights have been terminated (by the law), an alternate family caregiver (typically the grandmother) will be the caregiver we work with. In very limited cases, when alternative caregivers are unavailable, discharge from hospital leads to institutional care. Follow-up is conducted for all children by a social worker and a psychiatrist, for up to three months following discharge, with the (ideal) goal of leaving the child well established in a home care routine with a suitable school placement.

The intervention is organized in 4 modules, and each module is composed of a session of play therapy, which is filmed for 5 to 10 minutes, and then the VIT session is prepared with that video. The VIT session is usually performed during the same week as the play therapy. VIT expected that the caregiver will be able to recognize and recall what happened during the game, the conversation, their impressions and feelings before, during and after the play session. All parents in the intervention group receive four VIT sessions. Parents in the control group receive four session of dyadic play therapy without VIT.

Dyadic play therapy

The play unfolds typically in the common area or living room of the in-patient unit, around a table, where child, and visiting family, are invited to share in a game. Playing cards, Jenga, dominoes and other games are available for the family to choose. There are also puppets, tools and building blocks available. Families are also offered materials for handcrafts or painting. Thus, the play session opens various possibilities for each family to cooperate and converse with each other in a shared play task. Early sessions typically reveal various tensions, uncertainties, resistances, an absence of shared positive affect from both parents and children, and an overall unfamiliarity with the possibilities (and irresistibility) of play, slowly children and parents engage with one another and with the play materials, and the joy is palpable. They almost inevitably come to realize the developmental need for play (Winnicott, 1971). This is why during the hospitalization a space and time is offered for the development of play, through a permanent frame, which allows the children to feel safe. That is to say, the play session always takes place at the same time and a professional explains as many times as is required so that each caregiver understands the importance of complying with that scheduled time. Children will be waiting from the very beginning of the day that the family visits, for the play meeting with their caregiver(s). This framing allows patients to feel safe and secure as it helps to organize them in real-time and in a space that promotes the emergence of creativity (play) and mitigates isolating fantasies (which is the most common problem in these patients). During the play session, it is observed that in collaboration with either the main caregiver or their peers, patients can better sustain the adventure of playing, together with affections for the differentiated other, and pride in one's own integrative achievements.

It is our clinical impression that the shared game seems to facilitate an overall positive experience for children in the hospital. As one parent or family meets with a child in the play context, other children are observing nearby, and perhaps joining in. In this way, the play sessions with visiting families occurs twice weekly on average, and are a central activity in the hospital routine, serving to organize and contain children's feelings and anxieties. The incorporation of parents to work with the children, mediated by psychologists' real-time feedback, querying parents what they will focus on and intervening if misunderstandings arise, promotes the exchange of communication between children and parents, in time leading to new coping strategies. The central concern of the psychologists is to encourage parents to provide their children sensitive responsiveness, and to adopt a reflective parental role.

For early adolescents, conversation takes precedence over engagement in games, with an increased likelihood (compared to younger children) of imaginative conversation with parents or caregivers concerning home visits, and eventual discharge. Psychologists encourage parents and their adolescent children to engage in direct communication, collaboration and negotiation.

Feedback session – VIT

When a child is hospitalized what stands out most from the child's behavior toward the adult world are the maladaptive attitudes that the child has acquired. Caregivers usually feel frustrated, incompetent to deal with their children, discouraged and criticized. This means that VIT must first evaluate and reinforce the strengths and positive aspects of what is seen in the video, however scant this evidence may be. Finding it gives the caregivers the opportunity to feel effective again as parents, and this enables them to work on possible aspects of change or improvement. At the same time, parents are helped, often for what seems like the first time, to see strengths in their children and to create an image more adjusted to the reality of the child, which for most of the time is willing to have a playful encounter with his or her attachment figure, i.e., capable of providing protection and generating a sense of safety. But, as is often the case, what professionals in hospital witness, and what the parents know only too well, the child is often distractible, disorganized or angry during the family visits.

Two trained therapists perform VIT, these can be two psychologists or a psychologist and psychiatrist from the unit. It is common for caregivers, especially at the beginning of treatment, to avoid and/or deny conflicts along with devaluing the team or their own children. This generates feelings of frustration or helplessness and discomfort in the team. The therapists who prepare the VIT session must be able to recognize these difficulties, make them explicit to their fellow professionals during the preparation of the sessions, so that during VIT a collaboration may be established between the two therapists. This raises the possibility that when one of the therapists becomes confused or exhausted, they can signal to the other to continue with the session(s). In other words, two therapists work in tandem to ensure that caregivers are helped to feel safe, with minimal activation of past feelings of rejection and inadequacy. The register of the video analysis, planning and development of each VIT session is written on a sheet designed for this purpose, which can be included in each patient's medical record (**Figure 6: VIT record sheet**).

VIT provides a unique opportunity to promote reflective functioning in parents since they can, at the same time, on the video, see their child, themselves and the parent-child relationship from the outside, with a calm and supportive therapist (M. Steele et al., 2014). Parents are given the opportunity to stop the video as often as necessary and reflect on the internal states of mind of each participant (the child and the adults). Parents are granted the position that they deserve, that of being experts of themselves. In this way, VIT encourages parents to explore thoughts, feelings and deep-rooted ideas that many times are unconscious, or they are ashamed to verbalize aloud. Fear and shame have different complex sources that often arises in parents and are expressed as they view the videos of themselves with their children. The source material on the video is often seemingly benign as they cooperate in some fashion with the game, but what is aroused or activated is often deep fears that the child may explode or otherwise completely lose control or that they themselves lose control (as may have happened many times before). Sometimes memories of their own early childhood are activated and then therapists encourage the parents to link up these memories with the hopes and ideals they have regarding their maternity or paternity. When parents are able to connect with, express, contain and redirect their own childhood experiences, they are then able to empathize and better understand how their children may feel.

In every session, after making general comments on the video excerpt of the interaction that were shown, therapists continue by highlighting some strengths shown by the parent or child, drawing the parent's attention to some positive moment(s), however, minimal they may be. This is especially important in this situation, to establish and maintain good will. This is often pleasantly surprising for the parents because their attention, until the first video-feedback, has been largely focused on the problems that brought their child into the hospital unit in the first place. These positive moments can be as simple as observing a child's happy face when the caregiver acknowledges that she won a game of dominoes, the evidence of refraining from cheating from a girl who used to lie to her mother, the patience of both to achieve a common goal, or how the child is able to share her emotions when her mother asks assertively about her experiences. Many times, the adults had not realized the highlighted positive patterns, and they are greatly appreciative of the discovery that they are doing something good.

From this initial place of shared good feelings, it is possible to then ask if the caregivers would like to see an example of something they might like to change, i.e., some pattern of behavior in themselves or in their child, that if looked at carefully could lead to new ways they may find to connect with their children. When therapists sense that the parent is reluctant to accept an invitation to study a problematic piece of the video, the therapist will return to pointing out another strength in the parent or child. In this way, all caregivers are assisted in accepting the opportunity to look at problematic (or negative patterns), permitting the therapist to choose a problematic (but not too problematic) section of the video to which a straightforward piece of advice may be given to the parent. For example, a parent may be helped to see how they could be more patient and give the child more time, to complete the game, or explore the playroom. Or a parent may be helped to see how they could provide positive regard or feedback when the child does something well, i.e., as in 'good effort!'. Also, a parent may be advised on the virtue of asking the child to share his thoughts or feelings, or to share with the child his/her thoughts as a parent. The initiative to consider a possible change in behavior, fortunately, sometimes comes from caregivers themselves. And when caregivers pick up a specific aspect (i.e., lack of communication from the parent to the child, or lack of joy shown by the parent in the game), therapists will follow their lead, and praise the parent's initiative. It is important to be attuned with the possibility of change of the caregivers, or, in other words,

to scaffold successfully for them, so the video-filmed moments selected are pieces of interaction where caregivers are able to see the sequence, and easily imagine different possible behaviors they could try out in the future.

The emphasis is not on "correcting behavior" but first reflecting on the internal states of each (adult and child) and then thinking about new ideas, other possibilities, and what could happen if something different is done. Parents are advised by therapists that when trying to do something different, the hoped-for positive results may take time to appear. But the hospitalization provides a frame of reference where new things can be tried. This is discussed with caregivers, as it is common for them to be afraid of trying new patterns of interaction with their children for fear of precipitating a crisis. In this setting we use mentalization techniques to explore the inner experience of themselves and the child, and after that, thinking and practicing different ways of new behaviors with the parent; in this part we could stop the video and imagine what might happen if the parent said or did something different. This discussion often takes the form of a role-playing exercise, where the parent can play the role of the child, and the therapist may first take the role of the parent, before switching roles.

Because many sessions are held in a group context (with other parents), it is also expected that other parents may participate in watching the videos or joining in with the role play. The group context provides a rich range of social support and gives more opportunities to explore different meanings, feelings and alternative new behaviors. Therapists point out some ground rules for the group, including the goal that each speaker should assume a non-judgmental position vis-à-vis all others in the group. This is mostly well achieved because everyone has a child in the unit and is going through a similar challenging situation to a greater or lesser extent, and also some caregivers in the unit have more experience of the intervention and are thus able to provide emotional support to new entrants.

The four Play and VIT sessions that are done are different for each dyad in terms of objectives and situations that are explored, which means the intervention is tailored to the needs of the child, the caregiver and the possibilities of change that are observed during the treatment.

Nombre del niño
 Quién lo acompaña:

n° de sesión VIT:

EJES DE INTERACCION	Observación Juego Fecha Video:	Pasos	Fecha VIT: Minutos a mostrar:
Conexión Emocional		Observación video e impresiones generales	
Colaboración		Patrones Positivos	
Capacidad de poner límites y negociación		Patrones a mejorar	
Autonomía		Técnicas mentalización	
Organización de espacio y tiempo		Modo de relación a practicar	
Discurso narrativo		Preparación nuevo video:	

Figure 6: VIT record sheet