
Introducing psychosocial stimulation
to the treatment of children with
acute malnutrition in Mali: a
randomized clinical trial

Final degree project

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“There’s enough on this planet for everyone’s needs but not for everyone’s greed.” Mahatma Gandhi

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1. Abbreviations

UNICEF: United Nations Children's Fund

MAM: Moderate-Acute Malnutrition

SAM: Severe Acute Malnutrition

WHO: World Health Organization

W/H: Weight for Height/Length

W/A: Weight for Age

MUAC: Mid-Upper Arm Circumference

ETAT: Emergency Triage and Treatment

ITFC: Inpatient Therapeutic Feeding Center

ATFC: Ambulatory Therapeutic Feeding Center

MSF: doctors without borders/ Médecins Sans Frontières

HOME: Home Observation for Measurement of the Environment

PD/CD/SD/ED: psychomotor, cognitive, social, emotional Development.

HDIR: Human Development Index Ranking

HDI: Human Development Index

HIV: Human Immunodeficiency Virus

CIOMS: Council for International Organization Of Medical Sciences

2. Abstract

Background: Undernutrition affects 200 million children under five-years-old. The causes of malnutrition are multifactorial; in the mid and low-income countries, the causes include political, economic and environmental factors that provoke an unstable situation. Thus, producing food insecurity and insufficient health services. In these conditions, children suffer from a lack of emotional, social, motor and cognitive stimulation contributing to a worse children's condition, as well as, affecting the relationship between the child and their caregiver. The actual treatment of malnutrition is based on an effective nutritional protocol without taking into consideration the lack of stimulation. Nonetheless, in the last years, the WHO includes psychosocial stimulation to the nutritional treatment in their recommendations to treat malnutrition. Anyhow, evidence to support including psychosocial stimulation in the treatment of undernourished children is scarce. Several projects have tried to fill the evidence gap by conducting trials that show isolated improvements in the development of the children that received the psychosocial intervention when compared to a control group. With this study, we wanted to contribute to fill the evidence gap and add information around the effects of psychosocial stimulation in malnourished children.

Objective: The aim of this study is to examine whether anthropometric measures improve when psychosocial stimulation to food supplementation is added in children with malnutrition.

Design and methods: A randomized controlled trial will take place at the "Hôpital Femmes et Enfants", located in the city of Koutiala in Mali. 230 children between the ages of six months and fifty-nine months will be randomly assigned to the control (n=115) or the intervention group (n=115). The psychosocial intervention will consist of one session a week for a total of six weeks. Anthropometric measures such as weight for height and mid-upper arm circumference (MUAC) will be collected to do the statistical analysis adjusting them for all covariates.

Keywords: malnutrition, psychosocial stimulation, children, anthropometric measures, moderate-severe acute malnutrition.

3. Introduction

What is malnutrition?

The definition of malnutrition has long been discussed but still has not reached a general consensus (1). The general definition of malnutrition states that is a deficiency, excess or imbalance in a person's intake of energy and/or nutrients resulting in adverse effects on body composition, function and clinical outcome (2,3). In addition, malnutrition can lead to reduced immunity, increased susceptibility to disease and delayed development (4). In this work, the term malnutrition will be used in its undernutrition form.

Undernutrition is considered when dietary energy consumption is less than a pre-determined threshold. This threshold is country-specific and it is measured in kilocalories. (5) Undernutrition includes a range of conditions including acute malnutrition or wasting defined as low weight-for-height, chronic malnutrition or stunting defined as low height-for-height, and micronutrient deficiencies (6).

Malnutrition can be the cause of an emergency as well as the consequence of one. (6) Therefore, different approaches to tackle malnutrition will be required in each situation.

Epidemiology

In 2017, the number of undernourished people reached 817 million (5). In 2018, according to the United Nations Children's Emergency Fund (UNICEF), 49 million children under five years old were wasted and 149 million children were stunted. The highest prevalence of wasting in children under five years old is found in South Asia where 15.2% of the children under five are wasted. In addition, these data shows that one-quarter of all wasting children live in sub-Saharan Africa (Figure 1) (7).

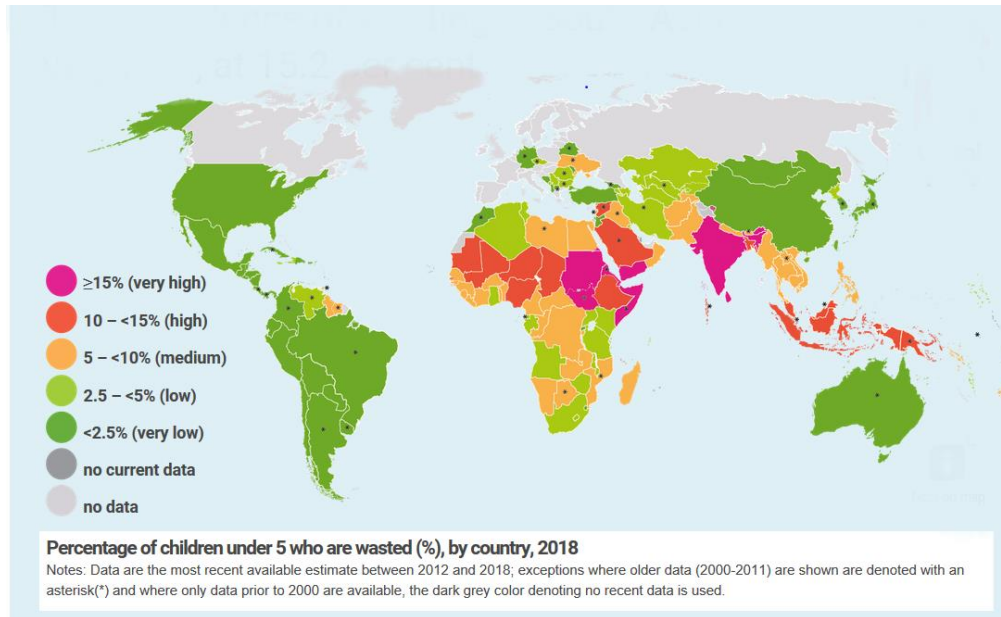


Figure 1 Map of wasted children under 5 in 2018 (7).
Source: UNICEF, WHO, World Bank Joint Child Malnutrition dataset, March 2019 edition

Globally, the prevalence of stunted children under five years of age is 21.9%; being south Asia and sub-Saharan Africa the most affected regions with more than 30% of their children under five years of age affected (Figure 2) (7).

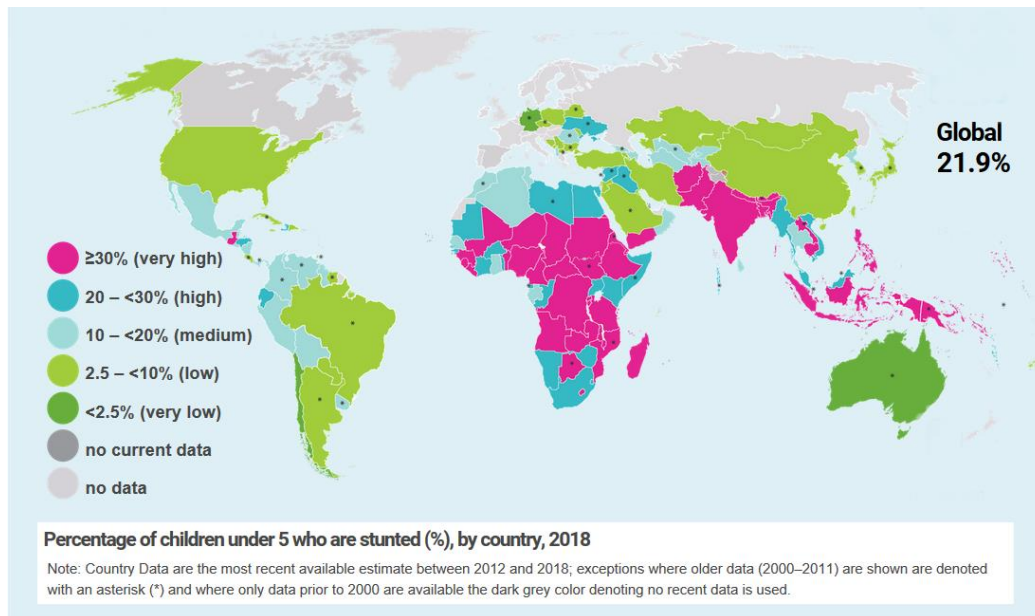


Figure 2 Map of stunted children under 5 years of age in 2018 (7)
Source: UNICEF, WHO, World Bank Joint Child Malnutrition dataset, March 2019 edition

Importantly undernourishment has shown a decreasing tendency globally but it varies depending on the region (4,5,7,8). In particular, there has been a steady improvement in the estimated global prevalence of stunting, from 32.5 % in 2000 to 21.9% in 2018

(Figure 3, left panel). However, at the same time, in West and Central Africa the number of undernourished children have increased from 22.4 million to 28.9 million (7,8).

Although the numbers globally show that the prevalence of undernutrition is decreasing nearly half of all the deaths (45%) in children under the age of five are attributable to undernutrition (6,7).

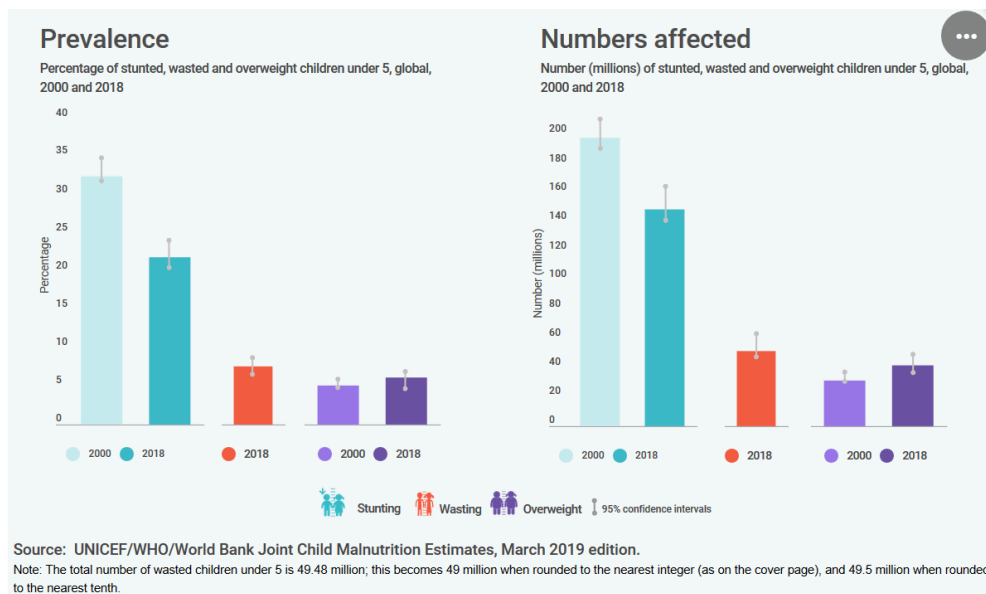


Figure 3 Prevalence of malnutrition under 5 (obesity taking into consideration)
Source: UNICEF, WHO, World Bank Joint Child Malnutrition dataset, March 2019 edition

Classification of malnutrition:

There are different types of malnutrition that vary in severity and the kind of nutrient deficiency. In addition, some types of nutrient deficiencies such as micronutrient deficiency and wasting or marasmus and kwashiorkor can also coexist together. The different types of malnutrition are summarized in the figure 4.

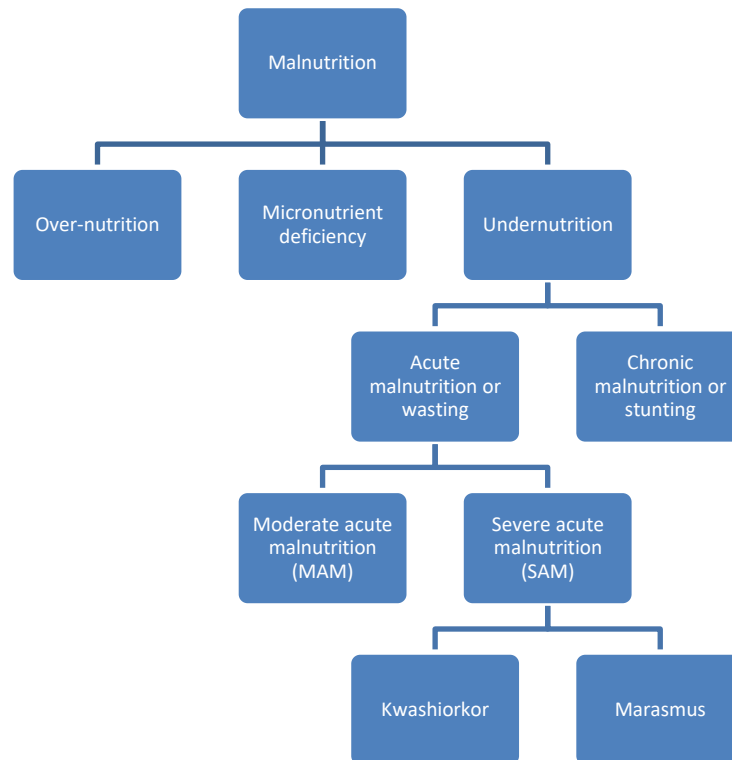


Figure 4 Types of malnutrition.

Over-nutrition is the cause of a dysregulation between the caloric intake and the energy consumption being the caloric intake significantly higher than the energy consumption. (9)

Micronutrient deficiency is the direct outcome of inadequate intake of vital vitamins and minerals. The most common micronutrient deficiencies are iron deficiency (which can lead to anemia) and iodine deficiency (which can lead to goiter or brain developmental problems in children) (10).

Undernutrition is a lack of intake of nutrition leading to altered body composition (decreased fat-free mass) leading to diminished physical and mental function (11). Undernutrition can be classified in chronic malnutrition also known as stunting where a child's height is too low for his/her age as a consequence of long-term nutritional deprivation; or acute malnutrition where a child's weight is too low for his/her height and the child's body wastes away (10).

Acute malnutrition or wasting can be moderate or severe. Moderate acute malnutrition (MAM) is defined when a child is between -2 and -3 Z scores in the weight for height/length chart. Severe acute malnutrition (SAM) is when a child's weight for height/length is below -3 Z scores in the charts (12). Table 1. Annex 1.

Table 1 Chronic vs acute malnutrition and their classification.

Z- Score	Growth indicators	
	Weight for Height/Length wasted (acute)	Height/length for age stunted (chronic)
Below -2	Moderate	Moderate
Below -3	Severe	Severe

Furthermore, there are two main clinical manifestations of SAM during childhood: edematous malnutrition (referred to as kwashiorkor) and non-edematous malnutrition or severe wasting, also known as marasmus.

These two types of SAM can coexist together. **Marasmus** is caused by a deficiency of calories and protein in the diet. The clinical signs of marasmus include bonny aspect, body temperature below normal and debilitated immune system which leads to infections. **Kwashiorkor**, on the other hand, is a condition in which a person consumes adequate energy but not enough protein. The outward signs of kwashiorkor are potbelly, dry unpigmented skin, reddish hair, low muscle mass, lethargy, failure to grow, and edema in the legs (13). Figure 5 shows the signs of Marasmus and kwashiorkor (4).

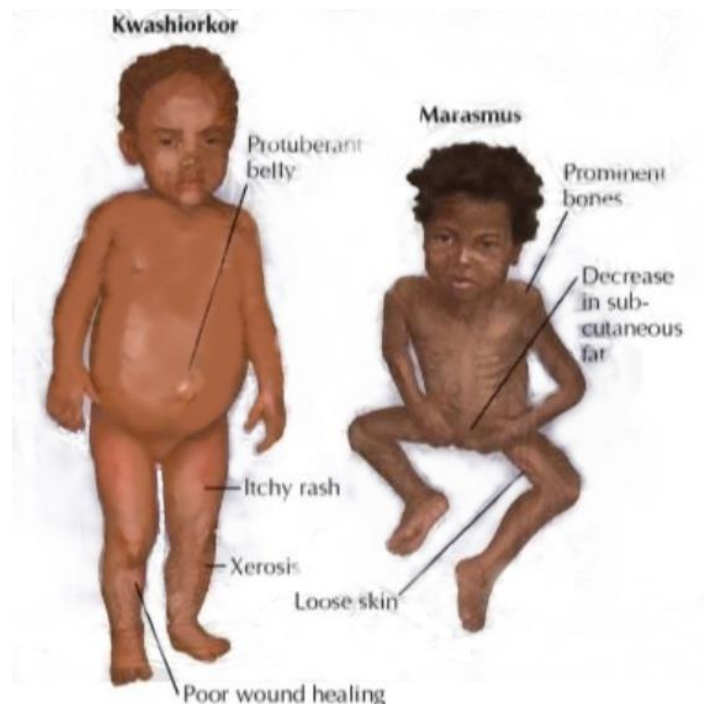


Figure 5 Marasmus and kwashiorkor clinical signs (4).

Causes of malnutrition in children:

Malnutrition can be considered the primary feature of an emergency due to a drought that causes famine or a consequence of social, economic, and political context that leads to conflict, displacement, and economic collapse (6,14). The causes of malnutrition are considered multifactorial. Economic or political factors such as wars reduce natural resources and cause a loss of control organizing humanitarian resources. This leads to inadequate access to food, inadequate health services and inadequate care for children which causes inadequate dietary intake and diseases such as infections ending up in a malnourished children (10). Figure 6.

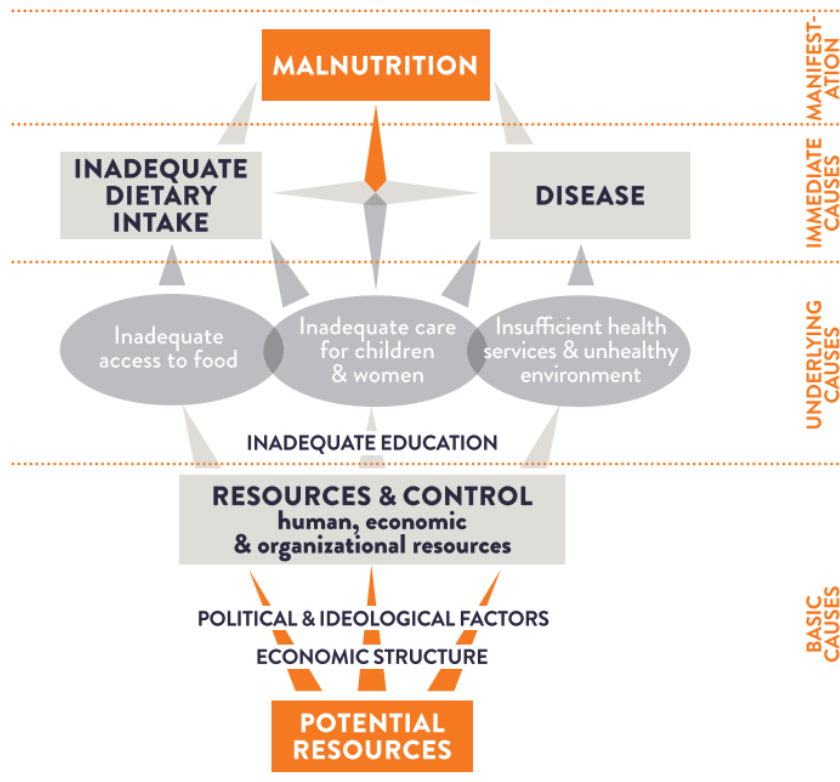


Figure 6 Causes of malnutrition.
Source: UNICEF

Causes of stunting include poor maternal health and nutrition (before, during and after pregnancy which includes suboptimal breastfeeding, inadequate infant and young child feeding practices (e.g. exclusive breastfeeding or low quantity and quality of complementary food) and infection (15,16).

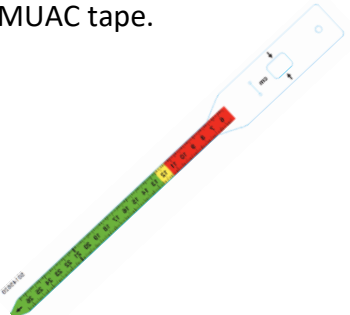
Importantly, these causes of stunting can also lead to wasting, as well as poor access to appropriate, timely and affordable health care, poor food security – not only in humanitarian situations but also in an ongoing lack of food quantity and diversity and lack of a safe sanitary environment including access to safe water, and hygiene services (15).

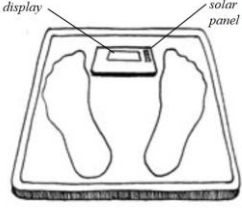
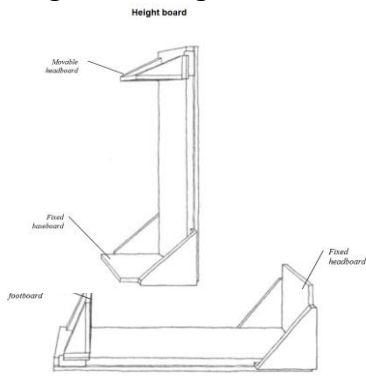
Diagnosis

The first step to diagnose malnutrition is identifying those at risk. To carry out this task screening signs that have been validated must be used. These signs include anorexia defined as a loss of appetite and progressive weight loss which reflects a dynamic process that requires a negative energy balance. Complications like repetitive infections or chronic inflammation are also considered a sign of malnutrition (11,17).

When the patient is identified at risk the diagnosis of malnutrition or wasting has to be confirmed. The most spread tools to carry out the diagnosis are the anthropometric measures. According to the World Health Organization (WHO) the ones used are included in table 2 (12).

Table 2 Summary of anthropometric measures used in the diagnosis of malnutrition

Anthropometric measure	Description	Tool
Weight for height/length (W/H)	Reflects body weight in proportion to attained growth in length or height. Used to identify acute malnutrition.	Weight for height/length chart. Annex 1. The x-axis shows weight in kilograms, and the y-axis shows length or height in centimeters.
Weight for age (W/A)	Reflects body weight relative to the child's age on a given day. Helps identify undernourished children.	Weight for age chart. Annex 1. The x-axis shows age, and the y-axis shows weight in kilograms.
Mid-Upper Arm Circumference (MUAC)	The mid-upper circumference is measured at the mid-point between the tips of the shoulder and elbow with a MUAC tape. Red: Yellow: Green:	MUAC tape. 
Height/length for age	Reflects attained growth in length or height at the child's age. Helps identify stunted children.	Height/length for age charts. Annex 1. The x-axis shows age, and the y-axis shows length or height in centimeters.
*Weight	Measured in kilograms using an electronic scale.	Electronic scale.

		 <p>UNISCALE</p>
<p>*Height/length</p>	<p>Measured in centimeters.</p> <ul style="list-style-type: none"> • If the child is two years or older we will measure height. • If the child is less than two years we will measure length. 	<p>Height and length boards.</p> 

*This anthropometric measures are taken in order to measure the other ones.

These indicators have standardized charts and tables depending on the age and sex of the children Annex I. These charts measure the Z scores if the child is below the minus 1 Z score in the W/H chart or below the -2Z score in the W/H and W/A charts it means that the children have a deficient growing. In this study we will be focusing on the age gap between six and fifty nine months.

It is considered severe malnourishment in children between 6 month and 10 year olds if MUAC is < 115mm (only between 6 months and 54 months) or W/H<3 Z (deviations) and/ or bilateral edema. If MUAC is between 115-125mm and the children have complications is considered severe malnutrition (6,18–20).

And moderate wasting if MUAC is between 115-125mm or W/H is 2-3 Z. (18,19)

Treatment

The WHO recommends that the treatment of children with acute malnutrition includes a nutritional aspect and a psychosocial intervention. Nevertheless, the psychosocial stimulation is a new recommendation and not all the guides include it.

The standard treatment will start when the patients enter in the health facility. The first step will be performing the triage during which all children will receive a cup of 10% sugared water depending on the weight. If the their weight is <10kg they will receive 50ml, if their weight is between 10-20 kg 100 ml and if their weight is more than 20kg they will receive 200ml (19).

It is important to monitor them at the emergency triage and treatment (ETAT) facility so at risk patients can be identify if they present hypoglycemia, hypothermia (19).

The next step will be to diagnose the children using the tools explained above. When children are diagnosed with SAM the patient will be admitted in an inpatient therapeutic feeding center (ITFC) or in an ambulatory therapeutic feeding center (ATFC) depending on the condition and stability (19,21).

The appetite test will be performed in children with SAM if they accept the food they will usually be treated in an ATFC if not they will go to the ITFC (19,20).

Usually, the ones categorized with severe malnutrition will go to de ITFC if they have any complications produced by infections or other illnesses (19,21).

The nutritional treatment in the ATFC is mainly ready to use therapeutic food (RUTF) in patients >6 months that comes in various forms biscuits (BP100®) and paste (Plumpy nut®). If there are any complications the patient will be referred to an ITFC (19).

The nutritional treatment is divided in 3 phases, the first two phases (initial and transition) will take place at an ITFC whereas the phase 2 will be done at an ATFC:

In the initial phase or phase 1, the objective is to restore metabolic functions, stabilize and treat or prevent complications. For that F75, an enriched milk formula with 75 kilocalories per 100 milliliters is used eight times a day for an interval between 3 and 7 days.

The transition phase lasts approximately 5. In this phase the patient can take RUTF or F100 a enrich milk formula that contains a hundred calories per a hundred milliliters 6 times a day.

Phase 2 consists on promoting rapid weight gain and catching up with growth. For that a combination of RUTF and local meals will be given within 4 to 6 weeks. This phase will be performed at home or in local ATFC.

Treatment of complications (infections) and concomitant diseases (HIV), vitamin deficiencies, vaccinations, will be also procured.

ITFC will be discharged of treatment when: W/H/length is ≥ -2 Z-score and they have had no edema for at least 2 weeks or MUAC is ≥ 125 mm and they have had no edema for at least 2 weeks (19,20).

Figure 7 shows the management of a child with malnutrition since entering the nutrition center.

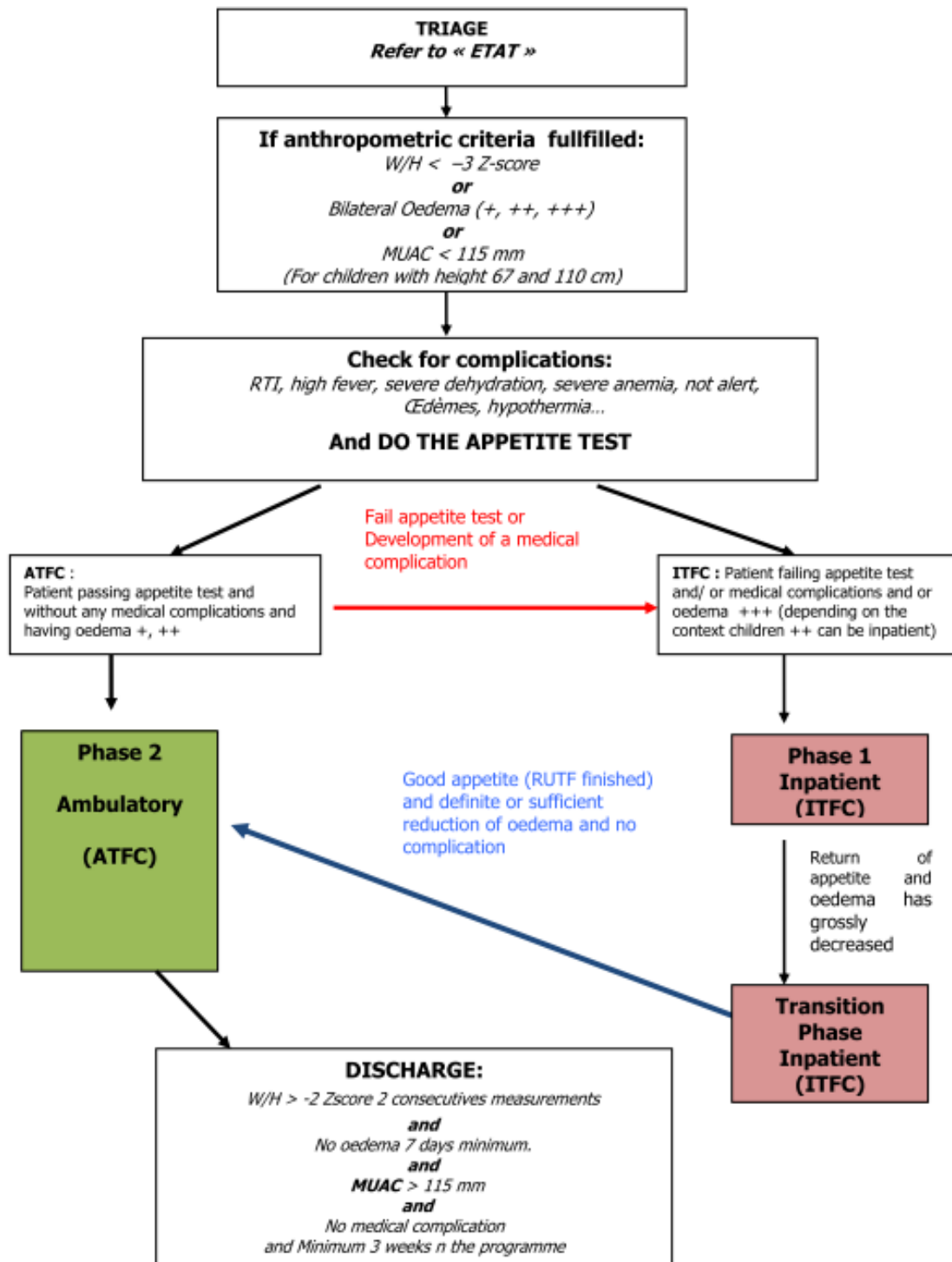


Figure 7 Management of children with malnutrition (19).

Relationship between malnutrition and delay growth

A great amount of the development of the brain happens in the first three years of life. It is also the time when the brain is the most responsive to stimuli (22). In these first years of life the brain develops rapidly through neurogenesis, axonal and dendritic growth, synaptogenesis, synaptic pruning, and myelination. These neuronal processes create the connections responsible for language, high cognitive functions, seeing and hearing. The Figure 8 shows a normal brain development related to the time that seeing, hearing and language should be acquired.

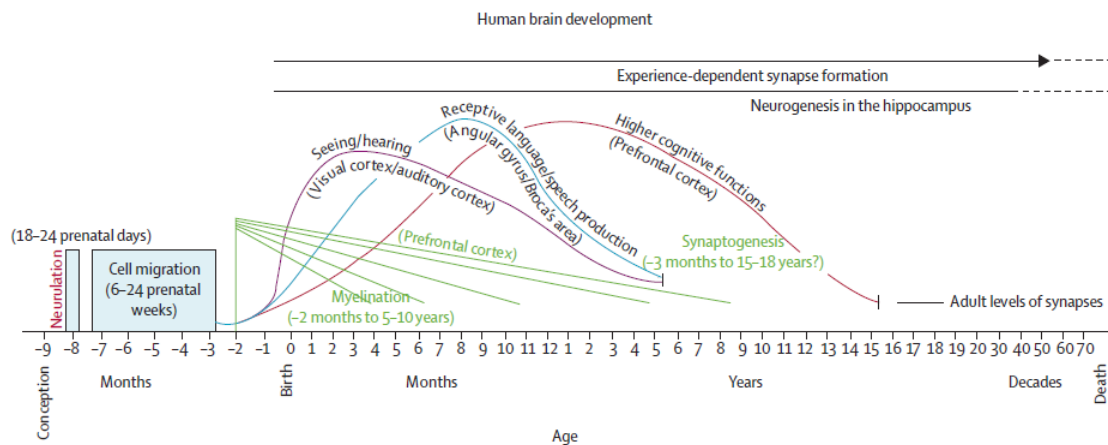


Figure 8 Normal brain development (23).

Nevertheless the development of the brain can be affected by psychosocial, biological and genetic factors. Early undernutrition and poor stimulation can affect brain structure and function since the body does not have the necessary nutrients to develop. Poverty is a major risk factor as it can lead to undernutrition and poor stimulation.

The lack of development can be observed by delay in growth, language deficits, later cognition or lower grades in school.

Over 200 million children under 5 years old do not fulfill their developmental potential. In these children some catch-up might take place, but most stunted children remain stunted through to adulthood which subsequently shows as low income, high fertility and these people have been proven to provide poorer care for their children (23).

Psychosocial stimulation

The idea of involvement between self and community was emphasized by philosophers like Plato and Hegel; but it was not until the 1890s when the term psychosocial appeared (24).

During the early nineties the psychosocial term referred to a connection between personality and social life. But in the 1930s and 1940s the concept that human behavior could be improved through coordinated series of psychological interventions was included under this term. This idea led to the possibility of stimulating psychosocial aspects as a therapeutic method (24).

Later on, the WHO adopted this term to explore the therapeutic advantages of using psychosocial stimulation in the development of children. Currently, the WHO defines the psychosocial stimulation as stimulation through sensory input as well as through emotional stimulation provided by a caregiver and it has been recommended as a therapeutic method (25).

Since then several organizations like United Nations Children's Fund (UNICEF) and doctors without borders (MSF) have created guidelines to include psychosocial stimulation in the development of healthy and undernourished children (26–28).

UNICEF developed two guidelines of psychosocial stimulation for children, one for clinical practice and another one for the participants. Both guidelines include recommendations to stimulate psychosocial aspects of children. These guidelines inform about the importance of the relationship between the caregiver and the child as well as giving ideas for play and communication. They also emphasize the importance of these practices in underweight or malnourished children to improve their health condition (26,27).

Other organizations such as MSF have also elaborated similar guidelines that include a minimum package with general activities or recommendations to stimulate psychosocial aspects in malnourished children or an extended set of activities for those places where a structure of psychosocial workers are already implemented (28).

These guidelines for psychosocial stimulation recommend listening to the kids, engaging in play activities with them, and giving advice to the caregiver as well as a play book or some directive questions adapted to the child's age. All these proposed interventions can be applied in the clinic as well as when the patient is discharged (26,27).

Nevertheless the evidences that psychosocial stimulation improves the health state of malnourished children are scarce. In this sense, during the last years, several studies

have tried to fill this evidence gap by conducting trials in specific regions with high percentages of undernourished children to improve its validity (29,30,39–44,31–38).

Some of these trials were designed to examine the effects of psychosocial stimulation in healthy children. However, the main conclusion of a meta-analysis of 29 studies was that in order to understand the implementation of psychosocial stimulation much more research is needed (36). One example of a randomized clinical trial was conducted in Indonesia. The results of the study showed that the experimental group displayed a significantly higher increase in intelligence quotient as well as a significantly larger reduction in attentional deficit. However, children in this experimental group were also given fortified milk. Therefore we cannot conclude that the improvement in cognitive functions is related to psychosocial stimulation (39).

Other trials conducted in Bangladesh, Ethiopia, Malawi, Jamaica, and Indonesia have examined how the psychosocial stimulation affects the cognitive and physical development of undernourished children. Most of these studies were randomized clinical trials performed in Bangladesh, although non-randomized control trials or control trials have also been described (41). Finally, another project designed as a cluster randomized trials was designed to be carry out in Malawi and Indonesia, although they have not been performed yet (35,40). Most of these trials targeted children under five years old with intervals between 6-24 months old and 6-59 months old.

To measure the development of the children, anthropometric methods such as MUAC and W/H were used (30,42). In addition some studies included a scale to evaluate the general development, such as the Bayley Scale II, the Griffiths’ scale or the Denver II screening test (Table 3). These scales measure different areas of the children’s’ development by testing the child and giving it a qualitative or quantitative score (29–31,42). To evaluate the quality of stimulation at home the “Home Stimulation Observation for the Measurement of the Environment” (HOME) questionnaire was also been used (34,43). During the last few years, these scales have been updated but they have not been used in studies where including psychosocial stimulation for children with malnutrition was studied.

Table 3 Child developmental scales.

	Concept	Items	Subscales or evaluated skills	Region where the scale was applied
Bayley II (1993)	Is a metric scale used to evaluate the psychomotor development of	Mental scale (178 items), Motor scale (111 items) and Behavior	Cognitive evolution, language and psychomotor	Bangladesh (29,30)

	children from 0 to 42 months old.	Rating scale (30 items).	development.	
Griffiths mental development scale. (1954)	Metric scale used to evaluate the development of children.	52 items per subscale, 260 in total.	Locomotion, personal-social, hearing and speech, eye and hand, and performance.	Jamaica (31)
Denver II (1990)	Screening test used to examine the progress of children between 0 and 6 years old	105 items	Gross motor development, fine motor skills, language and socialization.	Ethiopia (42)
HOME (1960)	Scale that evaluates the internal and external places where the child lives by an external observer.		Quality of stimulation at home.	Bangladesh (34,43)

Importantly, different approaches for psychosocial stimulation have been implemented in these trials, making it more difficult to compare the results. For example, some of the trials included weekly play sessions at home for 30 minutes or 1 hour per week (31,44), while other studies did a shorter but more intense intervention doing six daily group meetings for 30 mins and individual play sessions of 30 mins during a 2 week period in the hospital (33,42). In some interventions homemade toys were left in the home at each visit or exchanged, and the caregivers were encouraged to play with their children (42) or taught how to play with their children (31,44). Finally, in other trials, a curriculum of activities was given to the caregivers (33). Some of these activities encourage psychomotor development, other activities encourage cognitive development, and other activities encourage social and emotional development. Nevertheless most play activities encourage more than one area of development. Some examples of these play activities are shown in Table 4.

*Table 4 Play activities for children.
Adapted from MSF handbook of play activities.*

Skills targeted	Age	Activities	Materials	How to play
Psychomotor development (PD) Cognitive development (CD) Social development (SD) Emotional development (ED)	0-12 months	My reflection (PD, CD, SD)	Small mirror.	Offer the child a mirror and let him/her interact with it.
		Peek-a-boo (CD, SD, ED)	Hands.	The caregiver covers their face and says "where's she gone" and "here she is".
		Hanging mobile (PD, CD)	Black crayon, white paper, glue and yarn.	Draw simple contrasting white and black and leave the drawings in the play area.
	12-36 months	Body part recognition (PD, CD, SD)	Two people	Name a body part and ask the children to touch that part of their body. Sing "head, shoulders, knees and toes".
		Talking hands (PD, CD, SD)	Pictures of different objects.	Sit children in a semi-circle. Show the pictures to the children and ask them to use their hands to represent the object that you are showing them.
	3-5 years old	Giant bubbles with a rope (CD, SD)	Bottle of dishwashing detergent. Container with water 2 sticks 1 thin rope or piece of yarn	Mix 9 parts water and 1/2 part liquid soap. Let the mixture sit for an hour. Construct the bubble blower (with the sticks and the yarn). Finally, dip the hoop in the soapy mixture.
			Walking animals (SD,	Drawings or cut-outs of animals

		ED)		they are shown different animals. After showing one, everyone imitates that animal with their body, moving and making noise. Adults can give information of the animals while playing.
		Dwarf, Giant, Rabbit! (PD)	Large surface	The children are grouped and they begin to walk in a circle. They are asked to hop like a rabbit or take big steps like a giant.

There are also some differences regarding the duration of the trial and the frequency between visits. Some lasted 10 months being the visits less frequent after 6 months, and most of them did a control of the development of the child six months after the intervention started (30,31,41).

Results from these studies showed that those trials with psychosocial stimulation improved mental development like vocalization, cooperation and emotional tone (29,30). In one study the intervention group showed improvement in their developmental quotient, hearing and speech and hand and eye coordination (44). In addition, language was also improved at short and long term (41).

Regarding the locomotor function, no improvements were observed in the trials performed with Jamaican children (44), but a study performed in Ethiopia showed that psychosocial intervention can enhance the fine motor functions even when such standard dietary care is not available (41,42).

On the other hand, although mental or motor developments were unchanged after hospitalization at six months mark a slight improvement was observed (33). Nevertheless a review of two studies concluded that there were no differences between the control and the intervention group in the developmental quotient in two years' time (41).

Results obtained from the trials also showed that mothers' knowledge improved in rearing but not in hygiene and health matters (30,44). It is important to point out that home environment and child-rearing practices can be improved through community

based parenting education and play activities with or without food supplementation (34).

When children's body mass index and height improved it affected in their development independently of the intervention used (44) but the psychosocial stimulation alone did not improve the linear growth or the nutritional outcomes (41,42).

Combined interventions of food supplementation with psychosocial stimulation were significantly more effective than either alone (31). Improvement in gross motor functions when combined with standard nutrient-rich diet was seen (42).

In conclusion, the results from these trials suggest that in addition to include play activities and maternal education in the hospital treatment, longer term intervention with home visits should also be implemented (33). However, there are several limitations in these trials that should be tackled in future studies with undernourished children:

1. The comorbidities of the children enrolled in the different studies and if the comorbidities are taken into consideration are not specified.
2. These studies do not differentiate between children with chronic and/or acute malnutrition
3. These studies do not differentiate between children with marasmus or kwashiorkor.
4. Socio-economic environmental and political differences should be taken in consideration.
5. There is not a standardized scale to measure the development and the cognitive function.
6. These studies do not specify the kind of activities used in the psychosocial stimulation.
7. The time of training of the people implementing the psychosocial stimulation is not defined.
8. Some of these studies' designs provided low quality evidence.
9. Most of the studies do not support nutritionally the caregivers.
10. In many studies there is an important loss of the sample.
11. These studies do not specify if the people providing the psychosocial stimulation are been paid.
12. Only two studies evaluated children's environment to identify if it was stimulating or not.

Moreover the improvements in children with malnutrition were isolated not showing a significant relation between progress of children with acute malnutrition and psychosocial stimulation.

4. Justification

Childhood malnutrition is a major public health problem affecting 200 million children. It is an important cause of fatality and is related with low intelligence levels, behavior problems and poor school achievements that cause a waste of future assets for the community (14).

Nutritional and clinical treatments for malnourished children are well established and commonly used. However, although recommended by WHO, the benefits of psychosocial stimulation treatment in malnourished children are not well-established. This is due to the low quantity of trials as well as the limitations of the trials in the structure and the implementation performed so far. The reviewed studies agree that the information around this topic is scarce (29,30,39–44,31–38).

The benefit in growth upon psychosocial stimulation treatment is encouraging, but needs replication in further studies (33). This suggests that well-designed trials of psychosocial stimulation treatment in malnourished children are needed with different community-based approaches to scale-up the community based interventions (29).

In this scenario, and taking into account that ending malnutrition is the second of the developmental goals of UN after ending poverty, a well-established psychosocial stimulation treatment for undernourished children could potentially improve their developmental growth and future life.

With this protocol we want to contribute to the knowledge on how psychosocial intervention works and its effects on the treatment of children with acute malnutrition. We also want to explore the different ways to procure the psychosocial stimulation taking into consideration the challenges that an instable environment brings.

5. Hypothesis

Main hypothesis

In children with moderate acute malnutrition, psychosocial stimulation in addition to food supplementation improves the nutritional status (anthropometric measures).

Secondary hypothesis

Time of treatment in children with moderate acute malnutrition is shorter when psychosocial stimulation is added to food supplementation in phase 2 of the treatment at the ATFC, than in those children only treated with food supplementation.

6. Objectives

Primary objective

To examine whether anthropometric measures improve when psychosocial stimulation to food supplementation is added in children with malnutrition.

Secondary objective

To observe whether the time of treatment is shorter in children with moderate-acute malnutrition treated with food supplementation and psychosocial stimulation in comparison to children with moderate acute malnutrition treated only with food supplementation.

7. Methods

7.1 Study design

This study aims to evaluate the relationship between the psychosocial stimulation and the nutritional status of the children and is designed as a randomized clinical trial. The study will be performed in the “Hôpital Femmes et Enfants”, located in the city of Koutiala in Mali which has the support of MSF.

7.2 Study population: Mali

Mali is a country in the northwest of Africa surrounded by Algeria in the north; north of Guinea, Cote d’Ivoire and Burkina Faso in and Niger in the south; Mauritania in the northeast and Senegal in the west Figure .



Figure 9 Map of Mali (45)

Mali got its independence from France and Senegal in 1960, since then democracy was instituted. Although the official language is French there are thirteen more languages that are spoken such as Bambara or Peuhl. In addition to the different languages, there are nine ethnic groups. The majority of the people (94%) are Muslims.

Since 1990 Mali has suffered from migration and emigration due to poverty, conflict, food insecurity and droughts. Moreover, since 2017 Islamist terrorist attacks have been spreading killing hundreds of people in 2018. This situation deteriorated the social structure of the country obliging people to migrate to the south of the country (45,46).

Mali is situated 184 from 189 countries in the 2019 Human Development Index Ranking (HDIR) that measures human development based in life expectancy at birth, expected years of schooling, mean years of schooling and gross national income per

capita. Mali has a Human Development Index (HDI) of 0.427 in comparison Spain has a HDI of 0.893 (47).

Out of 3.33 million under 5 years old, 38% of the children are stunting, 26% are undernourished and 13% are wasted, it means that 77% of children under five years old in Mali are suffering from some kind of undernutrition.

The study population includes children between 6-59 months selected in the “Hôpital Femmes et Enfants” in Koutiala, Sikasso region, Mali. During the nutritional check-ups of the population in the health center consultations, children with acute malnutrition who fall within the inclusion criteria will be consecutively selected.

7.3 Sample size

In a two-sided test, with an alpha risk equal to 5%, and a statistical power of 80%, and assuming that the intervention will have a moderate effect (equivalent to a Cohen’s d equal to 0.2) we will need a sample size of 196 children. Assuming a drop-out rate of 20%, the final sample size will be 235 children. Samples will be recruited during a period of three months.

Computation was carried out with Prof. Marc Saez’s software based on the library ‘pwr’ of the free statistical environment R (version 3.6.2).

Sampling method

A consecutive non-probabilistic sampling will be done to pick the patients leaving the ITFC of “Hôpital Femmes et Enfants” in Koutiala who meet the study criteria.

7.4 Inclusion and exclusion criteria

Inclusion criteria

- Children between 6-59 months old.
- Signing de informed consent.
- Children who already have completed Phase 1 of the treatment.
- Weight for height or length, more than -2 Z scores in relation to the WHO child growth standards or W/H -3Z scores with a positive appetite test.
- MUAC more than 115 millimeters.
- Children who will be living in the city of Koutiala or in its surroundings for a year.

Exclusion criteria

- Comorbidities such as malaria, cancer, tuberculosis or endocrine diseases.
- Bilateral edema.
- Refusal to participate or to sign the informed consent.
- Children with developmental problems.
- Children with parents that do not understand the language, procedure.

*If the children have malaria when the outpatient visit is recollected or during the data recollection at 6 months he/she will be excluded.

7.5 Variables of the study

Dependent variables

The dependent variables are two anthropometric measures: Weight for height/length and MUAC. In order to get weight for height/length weight and height/length have to be measure separately.

Weight

The UNICEF electronic scale will be used to assess the weight of the children. The scale is powered by long-lasting lithium batteries. These will complete at least 400 weightings every day of the year for ten years.

If the child is less than two years old or cannot stand by his/her own tared weighing will be used. The weighing will be done with the help of the caregiver or an assistant following the steps described in the procedure

Length and height

Children's height/length will be measured in centimeters. In order to measure a child's height or length we have to take into account their age and the ability to stand upright.

- If the child is two years or older we will measure height.
- If the child is less than two years we will measure length.

1.1. Weight for height/length

After recording weight and the height of the child data will be included in a z-score chart. If the child is -2 SD in relation with the WHO standard, the child will be diagnosed with moderate-severe acute malnutrition. Annex I and II.

1.2. MUAC

The mid-upper circumference is measured at the mid-point between the tips of the shoulder and elbow.

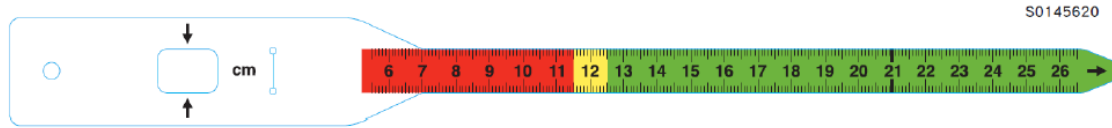


Figure 10 MUAC tape (12)

Table 5 How to read the MUAC tape.

Red	0-11,5cm	Severe malnutrition
Yellow	11,5-12,5cm	Moderate malnutrition
Green	>12,5cm	Not malnourished

Secondary dependent variable

Time of treatment will be measured in weeks. The researchers taking the anthropometric measures will record the start data and the final data of the nutritional treatment.

Independent variable

Psychosocial stimulation is a qualitative variable. It will be provided in the “hospital” by a trained psychologist for a total of 6 sessions during the outpatients’ visits. Each session will last an hour. Every visit will consist of two parts. In the first fifteen minutes the mother will be asked a few questions to see how the child is advancing and how she/he feels about it. In the next fifteen minutes the mother will be informed about different topics in relation with their child’s health such as nutrition and hygiene. The final half an hour will be used to play with the child and show them different games that they can reproduce at home.

Covariates

Age: the age will be measured in months and will be expressed as a quantitative discrete variable.

Gender: the gender will be presented as a qualitative dichotomous variable (male or female).

Fever: it will be measured by categorical dichotomous variable yes/no, with a calibrated thermometer in Celsius degrees. When the thermometer marks thirty-eight degrees or more it will be considered fever.

Malaria: it will be measured as a categorical dichotomous variable yes/no using a quick diagnostic test for malaria.

HIV: it will be measured as a categorical dichotomous variable yes/no using a quick diagnosis test for HIV.

7.6 Materials, procedure and data collection

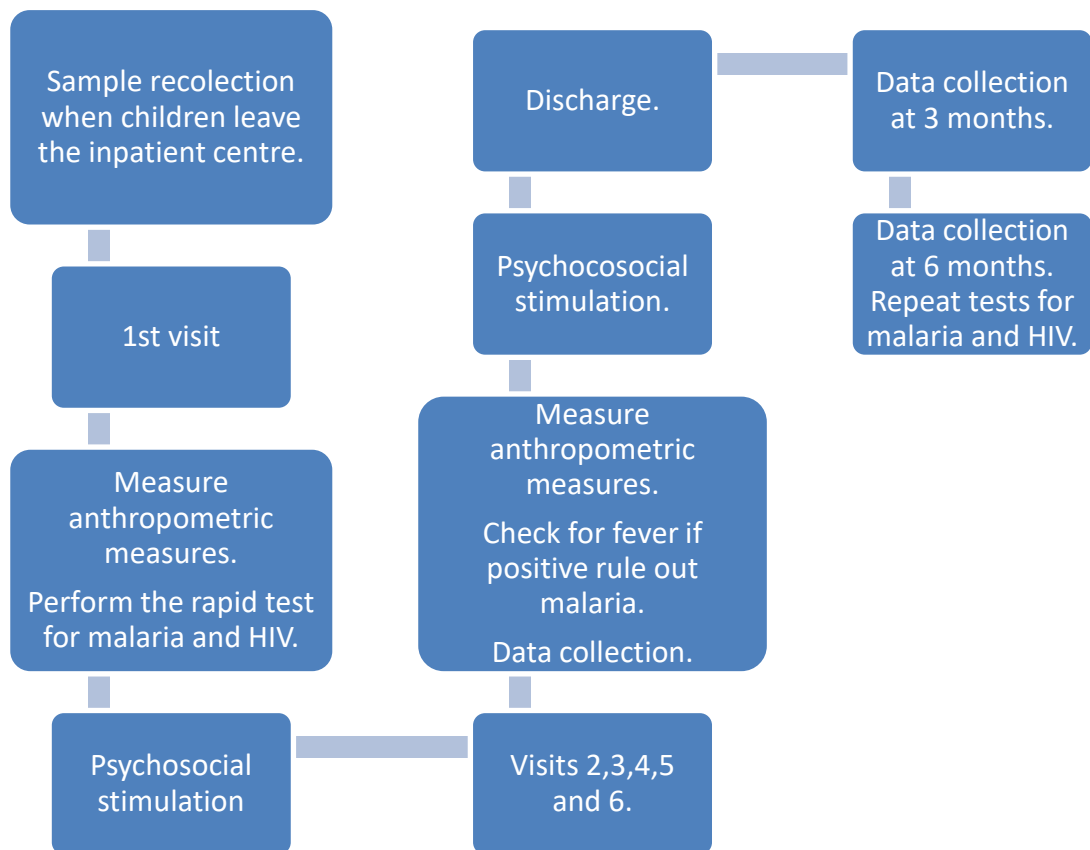


Figure 11 Procedure of the study.

Step 1: Measure the anthropometrical measures

When the child is discharged from the ITFC to the ATFC center their height and weight will be measured.

Weight: To measure the weight of the children who are less than two years old tare weighing will be used following the procedure described below (Figure 12)t:

1. Turn on the scale on by covering the solar cells for less than one second and wait until the display shows 0.0
2. Ask the mother to remove her shoes and step on the scale to be weighed alone first. She may need to adjust any long garments that could cover the solar cells of the scale.
3. After the mother's weight appears on the display, tell her to remain standing on the scale. Re-set the reading to zero by covering the solar panel of the scale
4. Give the mother her child to hold
5. The child's weight will appear on the scale: record child's weight

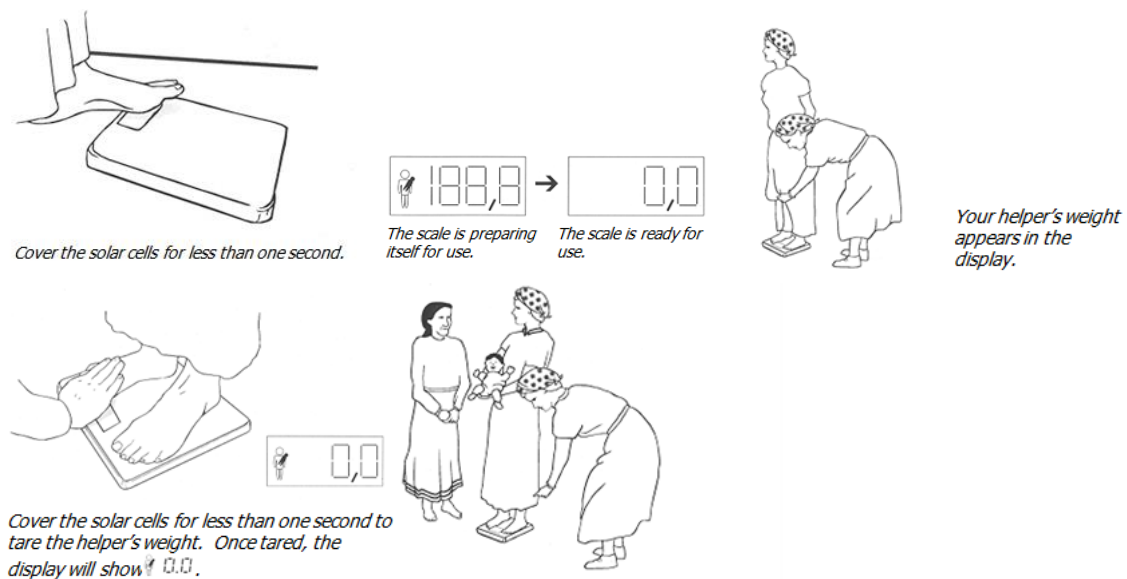


Figure 12 Tare weighing (48).

If the child is more than two years old and can stand still the following will be done.

1. Explain to the child that they will need to step on the scale alone and stand very still.
2. Undress the child.
3. Switch on the scale and wait until shows 0.0
4. Ask the child to stand in the middle of the scale. Do not hold or support the child.
5. The child's weight will appear on the scale: record child's weight in the data collection sheet. Annex II.

Afterwards the children's height/length will be measured:

Height/Length: If the child is two years or older we will measure height and if the child is less than two years we will measure length.

If accurate age is not possible we will measure length, if the child is less than 85 cm and height if the child is equal to or greater than 85 cm.

Height or length can be measured after weight as the child will be already undressed.

Length will be measured using a length board. The child will be asked to remove the shoes and unbraided any hair that could interfere with the measurement if he/she is not already undressed. The measurer will kneel on the child's feet to hold the foot piece. With the mother's/caretaker's help, the child will be laid on the board by supporting the head of the child. After the left hand will be placed on the child's shins. The measurer will press them firmly against the board. Then with the right hand, the foot piece will be placed firmly against the child's heels. Finally, child's length will be annotated in the data collection sheet Annex II.

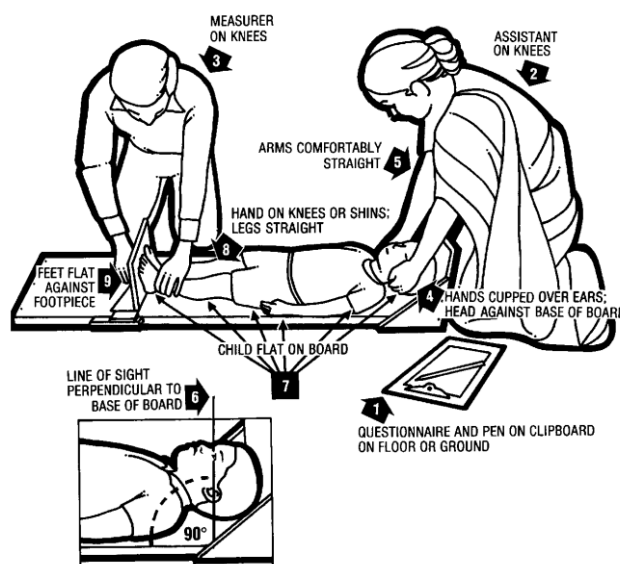


Figure 13 How to measure length (48)(12).

To measure height upright measuring board will be used. The child will be asked to remove the shoes and unbraided any hair that could interfere with the measurement. Then the measurer will place the child's feet flat and together in the center of and against the back and base of the board. After making sure the child's legs are straight and the heels and calves are against the board, the measurer will tell the child to look straight ahead at the mother if she is in front of the child. With the right hand, the measurer will lower the headpiece on top of the child's head. Then, making sure to push through the child's hair, child's height will be annotated.

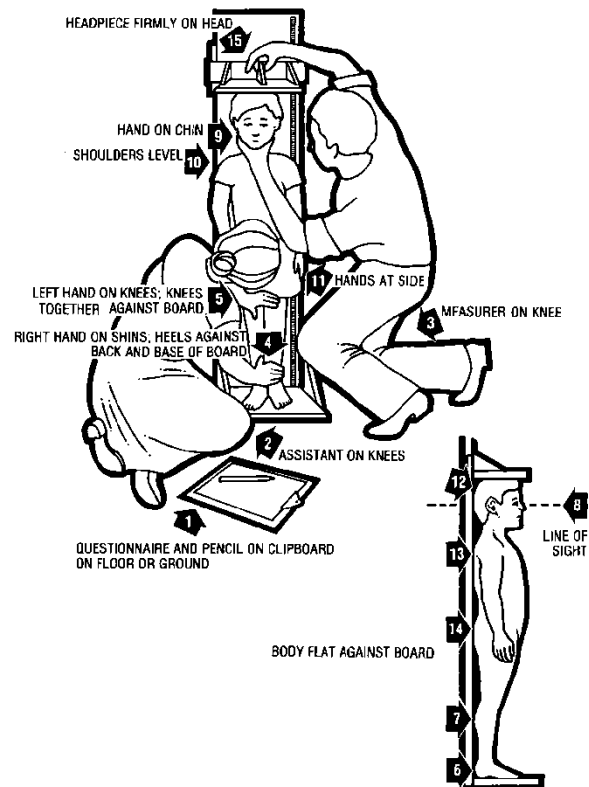


Figure 14 How to measure height (49).

The scale as well as the height/length board should be taken care by the professionals working there and make sure is clean and functioning correctly in order to be accurate in the measurements.

After recording weight and the height of the child the data will be put in a z-score chart. Annex 1.

MUAC: To finish with the anthropometric measures, MUAC will be measured using MUAC tape. The instructions to measure MUAC are the following:

1. Bend the left arm, find and mark with a pen the olecranon and the acromion.
2. Mark the mid-point between these two marks.
3. With the arm hanging straight down, wrap a MUAC tape around the arm at the midpoint mark.
4. Measure to the nearest 1 mm.(49)

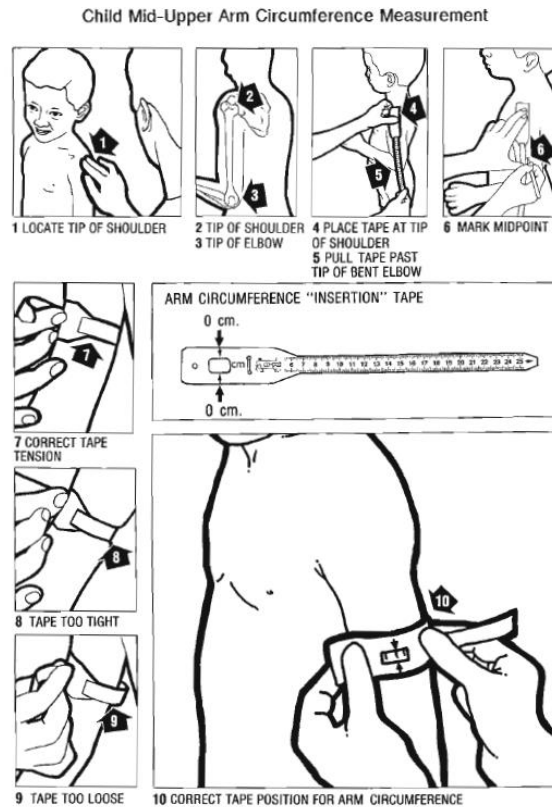


Figure 15 How to measure MUAC (49).

Step 1 will be repeated in every visit and will be performed in the intervention as well as in the control group, temperature will be also measured in all the visits. Afterwards psychosocial stimulation will be given to the ones in the intervention group. The measures will be taken by nurses who will be blinded from knowing which children will receive the psychosocial stimulation.

Step 2: screening for malaria and HIV

Screening for malaria and HIV: rapid tests will be used by trained personnel nurses or doctors in the first visit and six-month checkup, after the intervention is finished.

To screen for malaria and HIV the children will be puncture in the tip of the finger with a sterile needle then a drop of the blood will be placed in each device. After waiting for a couple of minutes, if the test shows one line as seen in the picture the test will be negative so in the data collection sheet (Annex II) it will be marked as no. If the test shows two lines it will be positive and marked as yes in the data collection form. The test for malaria also specifies the type of microorganism by marking the line next to the name. Figure X shows an example on how it will be seen.

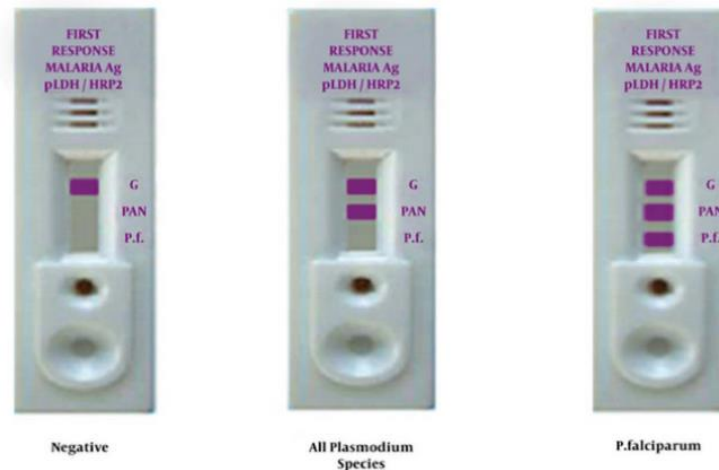


Figure 16 Example of a malaria rapid test.

This procedure will be done in the first visit and in the Note that if the children have fever in any of the visits a quick test for malaria will be performed.

Step 3: psychosocial stimulation

Psychosocial stimulation will be provided in the six visits at the AFTC by a trained psychologist. The psychologist will be provided with a copy of the handbook play activities of doctors without borders (Annex V) and materials to carry out the play session

- Visit 1: The first fifteen minutes the psychologist will explain to the caregiver what the intervention is about, the importance of it and if she has any questions before starting. The next fifteen minutes the psychologist will ask to the mother where she lives, how many kids they have and what their access to the food is. These questions will help understand the environment of the children and help the psychologist decide what aspects he/she has to reinforce. The next thirty minutes the caregiver and the psychologist will play with the children. For this part a play designed for the age will be taught by the psychologist. If there are materials involve the psychologist will taught the caregiver and the child how to fabricate it with the materials available. See annex II for play options.
- Visit 2: The first fifteen minutes will be used to ask the caregiver how she/he sees the child, if they are playing at home and how she feels. In this visit the psychologist will explain to the caregiver the importance of nutrition in children and the importance of giving the food packages to the child that suffers from malnutrition. The next thirty minutes will be spent teaching another game and playing with it.

- Visit 3: Repeat the first fifteen minutes as in visit 2. The next fifteen minutes will be used to talk about hygiene, teach the caregiver and child how to wash their hands Annex III and encourage potable sources of water. The last part of the stimulation will be playing with the child and the caregiver.
- Visit 4: First fifteen minutes as in visit 2 and 3. The information given during the next minutes will be about malaria, how is transmitted, its symptoms and the importance to take preventive measures such as mosquito nets or chemoprophylaxis. The last prevention measure is been spread around the country covering 80% of the children in 2018 so the psychologist should tell the caregiver that is available and how the child could benefit from it. This measure is taken from July to December. Afterwards as explained before play time with the child and the caregiver changing the play activity. If the child has other siblings or cousins his/her age tell the caregiver if they can bring one or two of them to the next visit.
- Visit 5: First fifteen minutes as in visit 2, 3 and 4. In this visit the information will be about the importance of social interaction with other kids. If there are other children in the family tell the caregiver to encourage them to play together or the caregiver can also teach them a game so they can all play. If the caregiver has brought other children for the last part we will play a game that includes all the people if not the game will be taught to the caregiver and the kid so they can reproduce it at home.
- Visit 6: In the last visit the psychologist will ask the caregiver how they see the child, if they have noted any improvement, how they feel, if they are more encourage to play with the children and how their relationship has developed over the last six weeks. It will be followed by a summary of the topics taught in the previous visits and the last part will consist of watching the caregiver and child play and giving them some tips to improve their interaction in relation with what the psychologist sees appropriate.

Note that different games promote different skills so each visit should target different skills. Also while playing, point out the importance of listening to the kid, making eye contact and touching.

Step 4: Data collection

Data will be collected at the beginning of the activity, before every visit, three months after the outpatient visits are over and six months after the sixth visit. Data then will be sent to the statistician anonymously, giving them the identification number of the children.

8. Statistical analysis

We will work at 5% risk ($p < 0.05$). All the analysis will be done with the SPSS version 25 (IBM).

Descriptive analysis

We will summarize the weight for height/length variable by the intervention groups (without psychosocial stimulation) using the mean, standard deviation, median and interquartile range.

The MUAC by the intervention groups will be summarized by proportions.

The difference of the treatment time medians between the control and intervention groups will be summarize using the median and interquartile range.

All the analyses will be stratified by the covariates. Age will be categorized from 6-9 months, 6-12 months, from 13- 36 months and from 37-59 months.

The survival curves for the time of the treatment for the control group and the intervention group will be estimated using the Kaplan-Meier estimator.

The covariates will be summarized by proportions, and in the case of age using the mean, standard deviation, median and interquartile range. In all cases, it will be stratified by the intervention groups.

Variate interference

We will test the difference in the means between the intervention groups of weight for height/length variable by means of the Student's t.

The difference of proportions between the intervention groups of MUAC will be tested by the chi square (or the exact Fisher's test in the case of in any of the cells the expected number of counts was lower than 5).

The curves of survival in the time of treatment will be contrast using the long-rank test.

All the analyses will be stratified by the covariates. Age will be categorized from 6-12 months, from 13-36 months, and from 37-59 months.

The difference of proportions (all the covariates except age) and means (age) of the covariates between the intervention groups will be tested by the chi-square (or the exact Fisher's test) and the Student's t, respectively.

Multivariate analysis

Although with randomization we control for the presence of confounding we will adjust the effects of the intervention on the dependent variables in multivariate models.

The association between W/H and the intervention will be assessed in a linear regression model controlling for all the covariates.

We will categorize MUAC in two different ways. In first place: no malnutrition or moderate-severe malnutrition and in second place non malnutrition-moderate malnutrition and severe malnutrition.

The effect of intervention on MUAC (categorized as pointed out above) will be assessed in logistic regressions controlling for all the covariates.

The effect of the intervention in the time of treatment will be adjusted using a Cox regression controlling for all the covariates.

9. Work plan and chronogram

This project will be completed in two years.

1. **Phase 1:** Protocol design and approbation (4 months from January 2020 to April 2020).

Activity 1: bibliography research was carried out during the month of January.

Activity 2: Protocol elaboration will be carried out by the research coordinator in addition to a psychologist and a psychiatrist, the last two will defined a psychosocial stimulation protocol that will be included in the main protocol.

Activity 3: Once the protocol is ready it will be presented to the CEIC of doctors without borders and after been accepted it will be presented to the CEIC at the “Hôpital Femmes et Enfants” in Koutiala, Mali.

2. **Phase 2:** Coordination and preparation, formation.

Activity 4: Meeting of the research coordinator with the director of the hospital and the 3 psychologists going from Spain will be done in order to get informed on how to coordinate the activity 6.

Activity 5: Training of the psychologist in how to implement the psychosocial stimulation will be done by the ones that designed the intervention protocol, as well as, a basic training in the political and social situation of the country and how to behave in emergency situations the training will take a month eight hours a day.

Activity 6: Coordination of the hospital. Training of nurses and doctors that will collect the data will be done, as well as an organization of the resources and the outpatient clinic in order to carry out the intervention. As they will collect anthropometric measures and signs in the data collection sheet the training will be of two hours a day for a week.

3. **Phase 3:** Sample recruitment, intervention and data collection.

Activity 7: The patient will be recruited from January 2021 when the malaria peak is finished until March of 2021, this will make it easier to avoid the children with malaria that fit in the exclusion criteria. The hospital has 185

pediatric beds; the expected time of recruitment for 230 children will be of 3 months.

Activity 8: the intervention will be carried out by psychologists as explained in the procedure,

Activity 9: data collection will be done by nurses who will measure the anthropometric measures, fever, as well as, perform the malaria and HIV quick tests at the beginning and at the end of the intervention. If the child has fever a malaria test will also be done.

4. **Phase 4**: Data analysis and interpretation of the results

Activity 10: a statistician will perform the statistical analysis.

Activity 11: Once the results are ready, a statistician hired by the research team will interpret the results and prepare an analysis. The results obtained by the statistical analysis must be confirmed by a steering committee and a statistician.

Activity 12: The research coordinator and the statistician will prepare a final report with the results, discussion and conclusion of the study.

5. **Phase 5**: Publication and dissemination of the study

Activity 13: Finally, when data is obtained and processed, results can be published and promulgated in written publications and international congresses such as the International Congress of Nutrition.

Introducing psychosocial stimulation to the treatment of children with acute malnutrition in Mali: a randomized clinical trial.

Chronogram

	Activity	Personnel	2020					2021					2022		
			J	F-M	Jn	Jl-A-S	O-N-D	E-F-M	A	M-Jn	Jl-A-S	O-N	D	E	F-M
Phase 1: Protocol desing and approbation															
1	Scientific bibliographic research	Research coordinator													
2	Protocol elaboration	Research coordinator, psychiatric and a psychologist.													
3	Protocol approval	CEIC, msf and hospital													
Phase 2: Coordination, preparation and dissemination															
4	Coordination and preparation of the research team	All research team													
5,6	Hospital coordination and training	All research team													
Phase 3: Sample recruitment, intervention and data collection															
7	Participant recruitment	All research team													
8	Intervention	All research team													
9	Data collection	Nurses and doctors													
Phase 4: Data analysis and interpretation of the results															
10	Statistical analysis	Statician													
11	Interpretation of the results	All research team													
12	Final article writing	Research coordinator													
Phase 5: Publication and dissemination															
13	Publication and disseminatio	Research coordinator and statician													

10. Ethical considerations

Medical research must respect the basic ethical principles of autonomy, beneficence, non-maleficence, and justice as well as the regulatory framework that regulates the investigation.

This study will be carried out taking into account the principles established by The World Medical Association in the 'Declaration of Helsinki of Ethical Principles for Medical Research Involving Human Subjects' (last actualization in 2016) which is universal and everybody has to follow. The Ethics of Research Related to Health care in Developing Countries, the Nuffield Council on Bioethics (2005), the Standards and Operational Guidelines for Ethics Review of Health-Related Research with Human Participants established by the World Health Organization, WHO (Geneva, 2011) and the International Ethical Guidelines for Biomedical Research involving Human subjects. Council for International organization of Medical Sciences, CIOMS (Geneva, 2016) will also be taken into account.

The *Ley 14/2007, de 3 de Julio, de investigación bioquímica* that establishes the legal framework for basic and clinical research will be respected. The study will also respect *the Spanish Ley de Autonomía 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica*. The patient or in this case the parents or guardians of the children have the right to be informed and have all the clinical documentation regarding the intervention been done and make the decision if they want to participate or not.

According to *Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos personales y garantía de los derechos digitales* only the researcher, his collaborators and the technical staff of the study will have access to the data. The data will be analyzed anonymously, and in case the results get published, it would be done respecting this Law.

The information about the intervention must be given both orally and written to the guardians of the children, and it has to be confirmed that the information has been well received and understood. Afterwards, parents or guardians of all participating children must sign the informed consent before the study is started (Annex IV).

The research protocol should be presented, evaluated and submitted to the Clinical Research Ethical Committee (CEIC) of MSF and to the CEIC of the nutritional clinic in Mali before the beginning of the study and when the study is finished in order to share the data and the results obtained from the study.

11. Limitations

Psychosocial intervention takes into consideration the individual situation of the person, team members will be trained to make sure psychosocial stimulation treatment is done similarly. However, it is possible that they take different approaches or find some aspects that they consider more important to work on.

The measuring instruments will be standardized and calibrated periodically to avoid errors in anthropometric measures. The research team will be instructed to report any broken or non-functioning material so it can be replaced.

This study will be carried out in a country where the social and political environment is instable, meaning that when the situation is unsafe the team will have to be put in a safe facility. During this time the project will be stopped and the data stored. The study will continue when the situation calms down and the research coordinator decides is safe to go back.

Patients will not be blinded, the ones benefiting of the intervention will know that they are receiving the treatment. To avoid the exchange of information between the intervention and the control group the psychosocial stimulation will take part in another part of the hospital. In any case the anthropometric measures for the control and the intervention group will be done by the same nurses in the same place so exchange of information may happen. The patients will be instructed to not talk about the intervention with other caregivers in the waiting rooms and nurses will be instructed not to ask patients.

One of the covariates could be the socio-economic background of the patient and the caregiver but taking into account the socio-economic situation of the country we have decided to leave it apart as most of the children attending the nutrition clinic will be from a poor background or from a place that has not resources.

All the data will be stored in paper and it will be computerized later, when all the data is collected. Papers can get lost leading to a loss of information, the research team will be aware to try to minimize the problem.

As the intervention takes into account the cultural and socio-economic factors of the population the results cannot be extrapolated to other countries. Nevertheless, if the results are positive the study may set a basic guideline on how to implement the psychosocial stimulation.

12. Budget

Table 6 Budget.

	Description	Quantity	Total	Cost
Staff				
Research coordinator	Is the person responsible for the study	1	35,000€/year x 2 years	70,000€
Statistician	He will carry the statistical analysis	1	35€/h x 40h	1,400€
Psychologists on the field**	They will provide the psychosocial stimulation	3	500€/month x 1,5 months x 3	2,250€
Psychologist/psychiatrist	They will develop the psychosocial stimulation curriculum	2	1,400€/month x 2	2,800€
Nurses	They will measure the anthropometric measures of the children at the 3 and 6 months follow up	2	300€/month x 5 month x 2	3,000€
Research team training		1 week, 2 hours/day	14h	380€
Materials				
HIV rapid test***	INSTI HIV Self-Test (3rd), bioLytical Laboratories Inc.	460	460x2€	960€
Malaria rapid tests***	Malaria P.f/Pan 25 Test. CARDS. (P. Falciparum.P. Malaria. P.Vivax. P.Ovale)	460	169,84€ for 25 x 19	3,227€
Play material	Papers, cardboard, glue	115		230€
Printing	Play handbook and the information sheet, consent and data collection	3,230,230, 230	2000 pages x 0,03€	60€
Publication and dissemination				
Publication in a journal				2,000€
International congress (International Congress of Nutrition)	Including transportation and accommodation of the person	1		3,000€
Total				89,307€

*Nurses, doctors, and materials for the anthropometric measures such as weight scales, height boards and MUAC tapes are not included as they are part of the standard nutrition treatment which is already implemented at the hospital.

**There are already psychologists working in the field so this cost will not be an extra if they perform the stimulation.

***Although rapid tests for malaria and HIV are already available in the hospital there are not enough to cover the necessities.

13. Feasibility

Médecins sans frontières is a non-governmental organization that has been working since 1971. Since it was founded, they have provided medical and humanitarian help in the main conflicts and natural disasters affecting the world as well as in epidemics and neglected tropical diseases that affect millions of people.

The hospital treats outpatient children with malnutrition which means that the materials such as electronic weight and height/length board will already be available as well as trained personnel like nurses or doctors. The part of measuring and writing down the data is already been done.

The fact that the hospital has also an inpatient department for malnourished children makes it easier to take the sample when they transfer from inpatient treatment to outpatient.

Nevertheless as doctors without borders is already working with the hospital makes it easier to send trained psychologists to implement the intervention and train the local staff.

14. Clinical and health care impact

Malnutrition in children under five years old is still a health problem affecting 200 million children around the world. Although food is the primary problem targeted there are other factors such as social or cultural that contribute to the lasting of the condition.

This study will provide more information about the effects of psychosocial stimulation in children with malnutrition which will help furthered the understanding and knowledge of how to approach children with malnutrition.

Although more research is needed if the psychosocial stimulation proves to be efficient it will cause a reduction of stunted children as well as more active assets for the community.

15. Conflict of interests

The authors declare that they do not have a conflict of interest.

16. Bibliography

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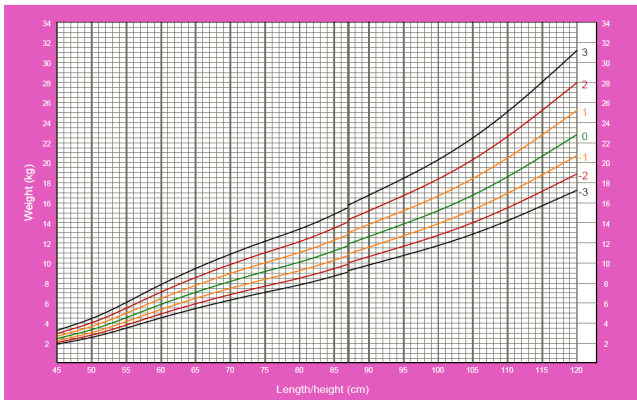
17. Annexes

Annex I: Anthropometric charts

Weight for height/length chart:

Weight-for-length/height GIRLS

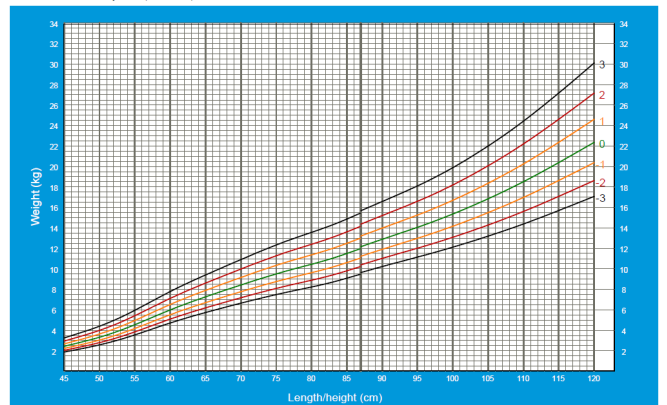
Birth to 5 years (z-scores)



WHO Child Growth Standards

Weight-for-length/height BOYS

Birth to 5 years (z-scores)

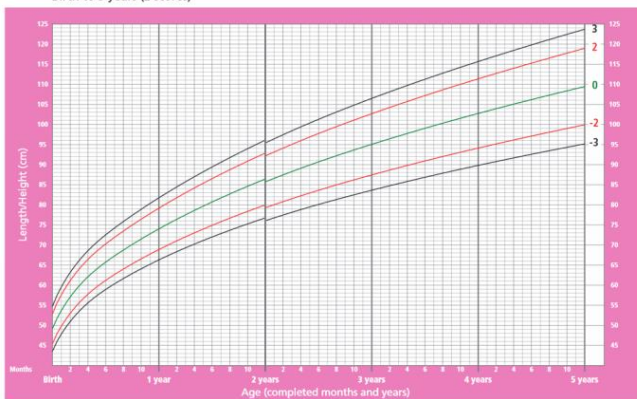


WHO Child Growth Standards

Length/height for age chart:

Length/height-for-age GIRLS

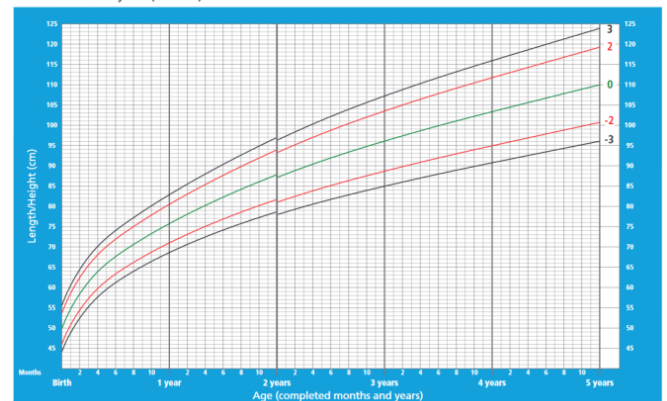
Birth to 5 years (z-scores)



WHO Child Growth Standards

Length/height-for-age BOYS

Birth to 5 years (z-scores)

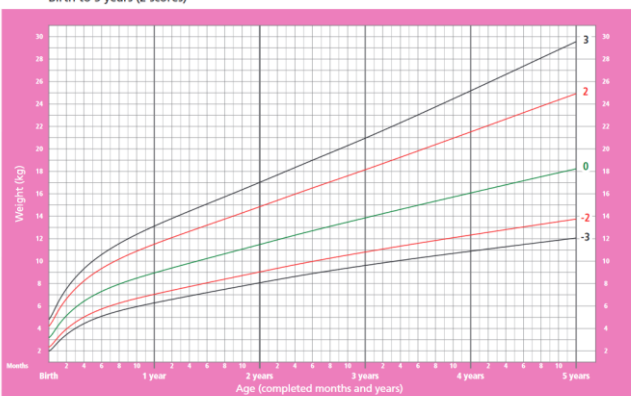


WHO Child Growth Standards

Weight for age chart:

Weight-for-age GIRLS

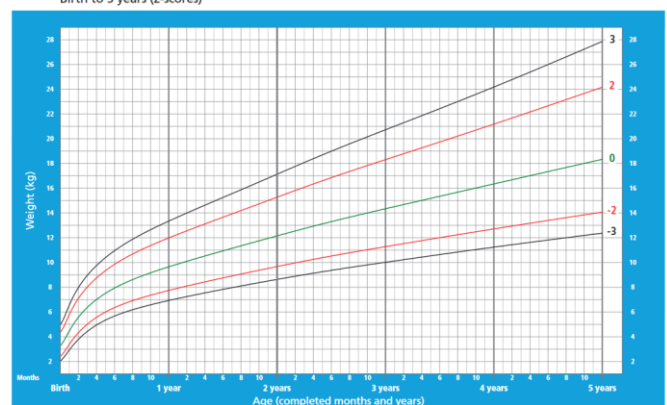
Birth to 5 years (z-scores)



WHO Child Growth Standards

Weight-for-age BOYS

Birth to 5 years (z-scores)



WHO Child Growth Standards

Annex II: Data collection sheet

Number of patient:

Professionals ID:

Starting data: / /

Finishing data: / /

Birth date (dd/mm/yyyy): / /

Visit 1:

6-month checkup:

Fever: Yes No

Fever: Yes No

Malaria: Yes No

Malaria: Yes No

HIV: Yes No

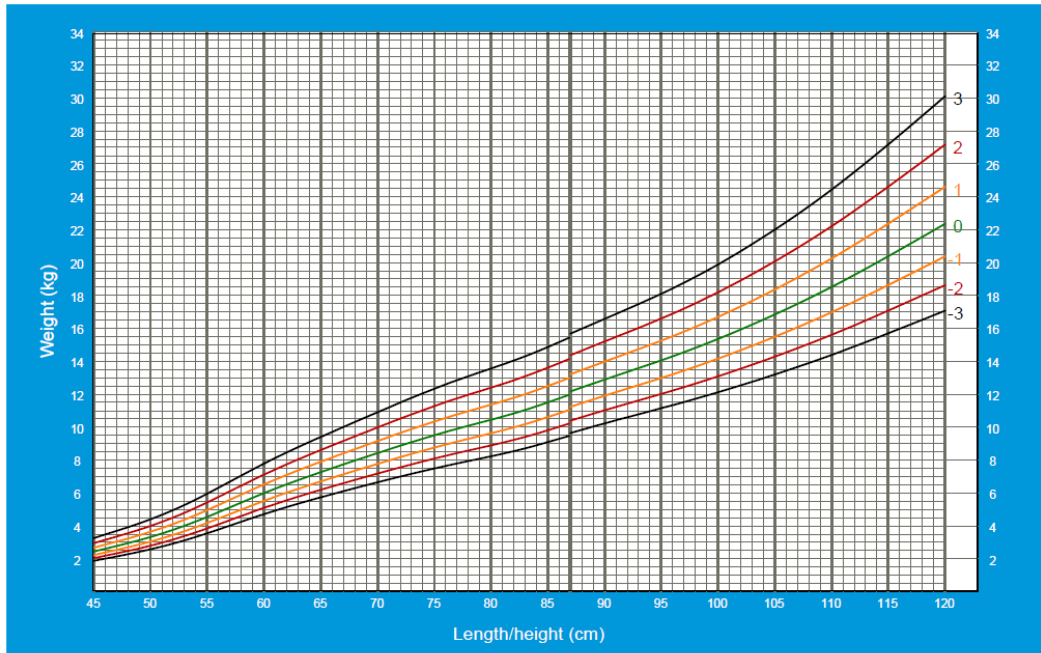
HIV: Yes No

Visits	Age (months)	Weight (kg)	Height/length (cm)	Weight-for-Height/Length (kg/cm)	MUAC (mm)	Fever (Yes/No)	If fever check malaria (Yes/No)
Visit 1							
Visit 2							
Visit 3							
Visit 4							
Visit 5							
Visit 6							
3-month checkup							
6-month checkup							

Weight for height/length charts:

Weight-for-length/height BOYS

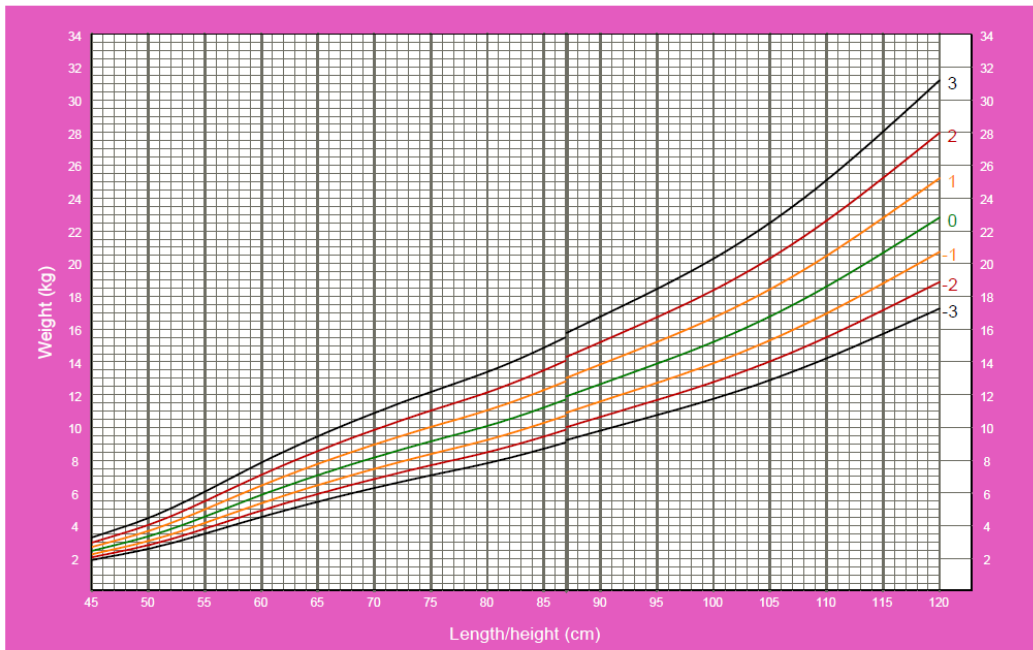
Birth to 5 years (z-scores)



WHO Child Growth Standards

Weight-for-length/height GIRLS

Birth to 5 years (z-scores)



WHO Child Growth Standards

Annex III: Project information

INFORMATION SHEET FOR THE PATIENT

The information sheet will be kept by the patient.

If necessary, the information sheet should be translated into the local language in this case French. If the patient does not know how to read the information sheet will be read to them and a verbal consent will be sign (Annex IV)

Thank you for taking the time to listen to our information about this study. As you might already know Médecins sans Frontières (MSF), jointly with “*Hôpital Femmes et Enfants*” is running health care projects in this area.

Today we are searching for people who want to participate in a study to understand if psychosocial stimulation will help children with malnutrition.

Firstly we want to make you know that the participation in this project is absolutely voluntary and in case of being accepted you have the right to refuse the informed consent or withdraw from the project without having any negative impact in your or your children’s health care and treatment.

Before deciding if you want to participate we ask to thoroughly read this information sheet and any questions that you have will be answered.

WHAT IS PSYCHOSOCIAL STIMULATION?

Psychosocial stimulation is a process where the children are stimulated by using games, by strengthening the caregiver child relation through listening, making eye contact and playing and by teaching the caregiver important topics related to the children health.

OBJECTIVE OF THE STUDY:

The objective of the study is to see if psychosocial stimulation improves the health of children with malnutrition.

DESCRIPTION OF THE STUDY:

This project is directed to children between six and fifty nine months old who suffer from malnutrition and their caregiver. It will include the children that have completed

phase one and transition phase of the treatment of malnutrition and are now entering the ambulatory therapeutic feeding center.

To realize this study we will include 230 children and their caregivers, which will be divided in two aleatory groups:

- Group 1: 115 children with their caregivers will receive an hour of psychosocial stimulation with a trained psychologist in addition to the standard treatment every time they visit the outpatient nutrition center to receive the nutritional treatment. It will feature six sessions one for each visit. And a control will be done three months and six months after finishing the treatment.
- Group 2: 115 children with their caregivers will receive the standard treatment of malnutrition without the psychosocial component. Their measures will be taken as done systematically with an addition of two more measurements at three and six months after finishing the treatment.

The professionals taken the measurements which include (weight, height, measurement of the mid-upper arm circumference and temperature) will be blinded meaning that they will not know what kids are receiving the psychosocial stimulation and what children are not receiving it.

During the first visit and the last one (the six month follow up) the children will be tested for malaria and HIV which includes a prick.

BENEFITS AND RISKS:

This study does not suppose a risk to the health of the caregiver or of the child. All the children in the study will be treated from malnutrition as is stipulated. This intervention is an addition to the standard treatment. If the intervention proves to have an effect this will be positive and harmless.

INTERRUPTION OF THE STUDY:

The study will be interrupted if the social conflict makes it difficult to carry out the normal activity of the hospital or if the area becomes too unsafe and people have to migrate from there.

CONFIDENTIALITY:

All of the data procured, both medical and personal, will be treated with the most confidentiality; following the Spanish law "*Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos personales y garantía de los derechos digitales*" only the researcher, his collaborators and the technical staff of the study will have access to the data. The patient data will be treated anonymously as the patients will receive a patient identification so the name of either children or caregiver will not be featured in any way.

ECONOMIC OR FOOD COMPENSATION:

No one participating in the study will receive an economic or any other type of compensation. All costs will be covered by the hospital and Médecins sans Frontières (MSF) meaning it will be completely cost free for the participants.

Thank you for your time and consideration, if you have any doubts or want more information you can contact the research coordinator.

[Name of Study Supervisor]:

[Phone number of study supervisor]:

Annex IV: Informed consent (verbal and written)

Written consent form:

I, _____ as the main caregiver of
_____ accept to participate on the clinical trial “Introducing
psychosocial stimulation to the treatment of children with acute malnutrition in Mali: a
randomized clinical trial” and confirm that:

- I have been informed by the doctor: _____
- I have read the information sheet and understood the content.
- I have asked any doubt related to the trial and they have been resolved.
- I have understood the benefits and the risks of the study.
- I have received a copy of the information sheet.

I understand that the participation is voluntary and that I can refuse or withdraw of the
study at any time that I want without any consequences.

Signature of the patient

Signature of the researcher

Place and date:

Verbal consent form:

If illiterate:

A literate if available witness must sign (if possible, this person should be selected by
the participant and should have no connection to the research team). Participants who
are illiterate should include their thumb print as well.

I, _____ as a witness confirm that the
caregiver of _____ has accept to participate on the clinical trial
“” and confirm that:

- I have witnessed the accurate reading of the information sheet to the parent of
the potential participant.
- I have witnesses that the caregiver asked any doubt related to the trial and
they have been resolved.
- I confirm that the caregiver has given consent freely
- I confirm that the caregiver has received copy of the information sheet.

I confirm that the caregiver has understood that the participation is voluntary and that he/she can refuse or withdraw of the study at any time that they want without any consequences.

Thumbnail of the caregiver:



Signature of the researcher:

Place and date:

HANDBOOK OF PLAY ACTIVITIES FOR CHILDREN

Tools to promote a healthy development in
children aged 0-12 years old



Lua Grimalt, psychologist specialised in children

Carmen Martínez Viciana, Mental Health Advisor OCBA

MSF OCBA 2015

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Types of play

Recommended activities

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My reflection

Musical bottle

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Guitar

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Treasure chest

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It's gone!

Through the tunnel

1-3 years

Characteristics

Types of play

Recommended activities

Tube talking

Catch the firefly

Recognise and sort

Painting sponge

Body part recognition

Colour instructions

Pretend wings

Little plane

Kangaroos

Talking hands

Musical statues

3-5 years

Characteristics

Types of play

Recommended activities

Giant bubbles with a rope

Walking animals

Box car

Every lamb has its partner

Animal parts

Dwarf, giant, rabbit

5-7 years

Characteristics

Types of play

Recommended activities

If I were a...

Walk on the wild side

Mystery bag

Statues

Blind fishing

Human knot

Around the enchanted lake

Standing in order on chairs

A tool for the job

Relaxing in my shell

Age 8 and upwards

Who's missing?

The tenant

From biggest to smallest

When I am you

My tree of myself

Theater of emotions

Seeing eye

Pin the tail on the donkey

Spiderweb

This is my circle

Treasure

Friendship papers

Listening circle

Turtle, dragon, person

V Annexes

Chart for Turtle, dragon, person

The tortoise tale

Table showing types of play by age

VI References

HOW TO USE THIS HANDBOOK

This handbook is a guide to children's play. It is designed to promote development and encourage interaction between children and their parents and significant adults.

The handbook aims to encourage the creation of spaces in which children are able, through play, to maximise four basic areas of development: psychomotor, cognitive, social and emotional.

It is recommended that the following criteria be kept in mind when selecting play activities:

- **Types of play suited to the child's stage of development:** children's play evolves as they develop, so for each age group, specific play interests are described that are suited to that stage (it is important to note that chronological age does not always match developmental age, so a game designed for three-year-olds, for example, will often be perfectly suitable for a child of four or five).
- The **type of development** mainly targeted by each game; whether motor, cognitive, social or emotional.
- The **type of play in terms of participants**; whether individual, parallel, associative or cooperative, bearing in mind that certain types of play only enter the picture once a particular stage of development has been reached. It is certainly true that from the age of five onwards, children are able to engage in all four types of play.

The following table lists the forms of play according to the stage of the child's development and the area stimulated.

WHY IS PLAY SO IMPORTANT?

Play is the most important 'work' done by children. It is not only fun, but is also the natural medium through which children share, negotiate, undertake, improvise and create, in a spontaneous manner and responding to their own challenges. What is more, play can also assist in improving children's self-esteem and help them overcome traumatic experiences.

Play is so significant to healthy child development that Article 31 of the Convention on the Rights of the Child recognises that all children have the right to engage in play and recreational activities and that all governments are to respect, promote and protect this right.

Unfortunately, many children around the world have no opportunity to play. MSF recognises the importance of promoting play activities for children who live in vulnerable and high-risk situations, since play involves a series of processes which encourage children's overall development.

The key functions of play in terms of child development are listed below.

Play encourages psychomotor development



Playing and experimentation contribute to the child's physical and sensory development, as well as helping to develop important functions such as balance, self-perception, control of the body, fine and gross motor skills, etc. If children are given the chance to experiment freely with their body, they will gradually increase their abilities and confidence in what they are able to do at this stage of their psychomotor development. Games involving use of the body encourage children's motor coordination and their use of spatial perception, hearing and rhythm.

Play encourages cognitive development



Play helps to stimulate symbolic thought and reasoning skills. It exercises attentiveness and memory, as well as stimulating creativity and the imagination. Through play, children create and develop thought processes which encourage creativity. By creating imaginary scenarios and imitating everyday experiences, children are capable of creating new scenarios and situations. Children often use real life elements as a basis for play, transforming it in the process. In this way, they learn to contrast phantasy with reality. Play activities also encourage the development of language, logic and mathematical skills and abstract thinking.

Play encourages social development



During their early years, babies and small children mainly interact with their parents or significant adults. Children develop their ability to play through these first games with adults. We know that from their first months onwards, babies' favourite activity is playing with their adult carer. They enjoy being sung and talked to and cuddled. Thus, it is through playing that babies establish their first relationships with others.

Next, children learn through play to also interact with their peers, gradually getting establishing closer relationships with the people around them and engaging in daily interaction. Through play, they learn to recognise the agreements and norms within their social group. Their relationships with other children are also stimulated through play, as many games require several participants. In addition, playing boosts children's social development, as when playing they imitate the interpersonal relationships they see around them and learn how to recognise themselves within their environment. It also builds communication and cooperation. Children learn behavioural norms through play activities, which has a positive impact on their moral development

The simple act of accepting the rules of a game or a result dependent on luck is in itself a real exercise of consensus and understanding on the part of all the players involved. In this way, playing unfolds a sequence of situations which encourage the development of such essential everyday skills and capabilities as creativity, taking risks, effort, sense of humour, moral and critical thought.



Play encourages emotional development



As an instrument of emotional expression and control, play leads to personality development, emotional stability and mental health. Children use games to test reality and explore emotion and roles. When playing, they create special spaces and situations in which we become fearlessly involved, because we know there is no danger. This calls for a specific psychological attitude on the part of the person playing, based on the conviction that whatever the game involves, it will never, under any circumstances, be judged or dangerous to the players. If the space for play is protected, its successes are associated with positive emotions and mistakes, far from being associated with failure, become opportunities to try again, thereby creating healthy defences against frustration. By recognising our limitations and trying to learn how to overcome them, we learn trust, empathy and optimism and how to experience mistakes as learning opportunities

For children who have experienced emotionally stressful situations, it is very important that these safe spaces are available, as they enable them to release pent-up feelings and frustrations. In cases such as these, it is seen as particularly helpful to include the family or a significant adult in play activities, as this strengthens the emotional interaction between the children and their carers, which is essential to the child's development.

Play is clearly a powerful tool with which to practice and learn the skills needed to promote thought, tolerance, creativity, respect, gender equality and resilience, all of which help to protect the child's mental health. This is why MSF encourages play activities, since they are not only synonymous with promoting child development, but also have preventive and therapeutic functions.

Age	Activity	Area of development targeted			
					
0-1	Piece of cloth	X	X		
	Hanging mobile	X	X		
	My reflection	X	X	X	
	Musical bottle	X	X		
	Music with spoons!	X	X		
	Guitar	X	X		
	Put it in, pull it out	X	X		
	Treasure chest		X		
	Peek-a-boo!		X	X	X
	It's gone!		X	X	X
	Through the tunnel	X	X	X	
1-3	Tube talking		X	X	
	Catch the firefly	X	X		
	Recognise and sort	X	X		
	Painting sponge	X	X		
	Body part recognition	X	X	X	
	Colour instructions	X	X	X	
	Pretend wings	X	X		
	Little plane	X	X	X	
	Kangaroos	X	X	X	
	Talking hands	X	X	X	
	Musical statues	X		X	
3-5	Giant bubbles with a rope		X	X	
	Walking animals			X	X
	Box car	X		X	
	Every lamb has its partner		X		
	Animal parts		X		
	Dwarf, giant, rabbit	X			
5-7	If I were a...	X	X		X
	Walk on the wild side	X	X		
	Mystery bags		X	X	
	Statue:	X		X	
	Blindfold fishing	X	X		
	Human knot	X	X	X	
	Around the enchanted lake			X	X
	Standing in order on chairs	X		X	
	A tool for the job		X		X
	Relaxing in my shell				X
8 y +	Who's missing?		X	X	
	The tenant			X	
	From biggest to smallest	X		X	
	When I am you			X	X
	My tree of good things				X
	Theater of emotions			X	X
	Seeing eye			X	X
	Pin the tail on the donkey	X		X	
	Spiderweb			X	
	This is my circle			X	X
	Treasure			X	X
	Friendship papers			X	X
	Listening circle			X	X
	Turtle, dragon, person			X	X

WHAT ARE THE DIFFERENT FORMS OF PLAY?



Play with adults

The child interacts with an adult, which can be a parent or another person (from birth onwards).



Individual play:

The child or infant plays alone, not interacting with others (up to 12-18 months). During this phase it is normally the parent or main carer who encourages the child to engage with other children of the same age.



Parallel play:

This is a form of play which is both individual and accompanied at the same time (one to two and a half years). Children play alongside each other but do not interact or share their toys. In other words, their activities are not linked.



Associative play:

This is the first attempt at collective activity (from two and a half years on). Children play with the same materials in the same space, but they do not create together.



Cooperative play:

Children are able to create a space in which they play together. The game depends on the participation of all those involved.

FRAMEWORK

Safety A safe environment for play can encourage communication between child and adult about the emotions the child is experiencing. When this communication takes place, adults are able to provide a comfortable environment, guidance and context for children's nascent understanding of the stressful events affecting their lives and the emotions aroused by such events (Haight & Sachs, 1995).

Play and trauma Symbolic play (make-believe) involving children and their carers can offer an opportunity for children to understand the traumatic events they have survived or witnessed, or to process with abuse, illness, accident or other highly stressful or traumatic experiences. Play therapy has in fact proved one of the few effective means of treating children exposed to traumatic situations. Nevertheless, children who have been exposed to trauma are less interested in play (Kramer & Scheafer-Hernan, 1994). In other words, the time when the child has most to benefit from symbolic play is also one when he or she is less interested in playing.

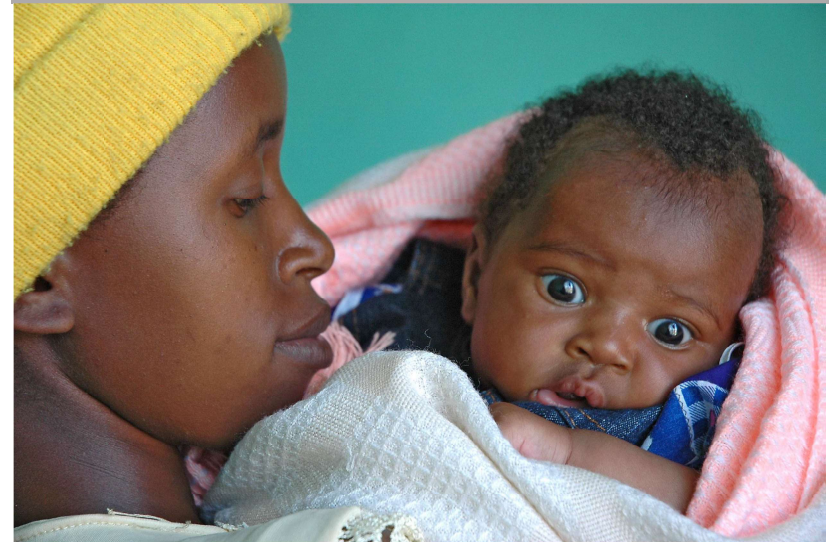
Thus, for symbolic play to be of assistance to children exposed to high levels of traumatic stress, it needs to take place with the support, structure and guidance of a trusted adult (Singer, Michnick, Hirsh-Pasek, 2006)

In tune with their development When proposing activities for children, it is important to know what stage of development they are at, so that their needs can be understood in relation to their age. This will enable us to act in accordance with the child's pace of development, without causing confusion or frustration.

Traumatic situations often leave an impact on some area of the child's development. Professionals, parents and responsible adults should therefore be alert to the child's general state of being, so that they can then assess the need to stimulate any aspect of her development that seems particularly affected, with priority always being given to the child's wellbeing and protection.

This handbook describes the basic characteristics of each stage of the child's development and games suited to each stage. It should, however, be borne in mind that although broad patterns exist, each child has his or her own pace of development which may be different from that of other children the same age. Some learn to talk sooner than average, others take longer to start walking, and so on.

Activities for children aged 0-12 months



Characteristics of this stage

Attachment

During the early years, mothers, fathers and teachers have an extremely important role to play in safeguarding and facilitating children's play activities. It is therefore essential for the adult to adopt an open, confident and positive attitude when playing with children, offering resources, paying attention to their needs and knowing how to enjoy the situation and the moment. This attentive, trusting attitude will enable the adult to accept the child's need either to play with them or stop doing so and will allow them to enjoy sharing in the child's dreams and fantasies. In this way, they will be able to create a space of trust, freedom and creativity in which the child can grow and develop.

The most important thing is for the child to have close, loving, physical contact with her mother or main carer. Everyday moments of caring and interaction are highly significant opportunities for communication and emotional nurturing. When these activities are carried out carefully and respectfully, letting the child know what is about to happen, the child gains the necessary emotional security to then concentrate on playing and exploring the surrounding environment.

The senses

Children's earliest experiences are mainly physical and sensorial, as are their communication and expression. During their first months, babies learn about the world around them through their senses. Play involving different sensations, such as smells, colours, forms, textures or flavours, activates different neuronal connections, delivering information which stimulates sensorial, emotional, social and cognitive development.

Thus, bodily experience is essential to developing a sense of self; the child needs to be able to move freely, confidently and in safety.

Types of play

Free movement

It is advisable to give children plenty of freedom to move during their first year of life, observing how they respond to the space around them and providing appropriate elements for them to explore, investigate and handle. It is important for the child to experience new motor skills, using a variety of objects of different sizes, textures, weights, temperatures and so on. Cognitive functions are built by direct manipulation of objects.

If we allow children to move freely within a safe space, the sequence of motor development is as follows:

- If left face-up on a flat surface, the child will learn to twist her own body into a face-down position and raise her head, thereby strengthening her back and neck muscles. The child is then able to turn over again into a face-up position.
- the child supports the weight of her upper body with her arms, which will in future enable her to **roll, slither and finally crawl**.
- The next stage is reaching a **semi-sitting position, supported by one hand**.
- Kneeling position with upright torso, enabling the child to **stand up while holding onto** or leaning against an object or piece of furniture.
- The child is finally able to **stand without assistance** and from then on learns to walk.

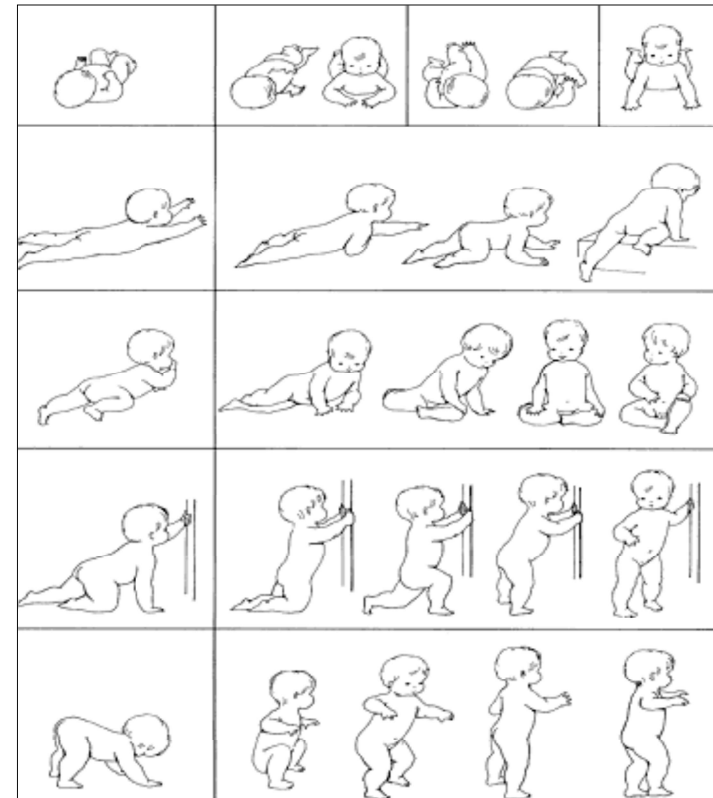


Image from the book *Moverse En Libertad* by Emmi Pikler

Materials

The objects presented in the beginning should preferably be soft, flexible ones which the child can grasp, and better still if they make a noise (paper, cloth). Next, it is good to offer harder objects which the child can grasp, first with one hand and then with both. This leads to their first interaction with objects: picking them up and throwing them. During their first year, children look towards where the object has fallen. In this way, they learn to associate the direction of the object with its location, even though it disappears momentarily or the child immediately forgets it because something else has attracted his attention and also needs to be discovered, and the same finding-throwing process continues.

Recommended activities

Piece of cloth

Age: 0-6 months



Specific skills targeted: visual stimulation, hand-to-eye coordination.

Materials: piece of cloth, preferably in contrasting colours.

Activity: Place the baby lying on the floor (with a sheet or blanket underneath if the floor is very cold or hard). Show the child a piece of cloth in contrasting colours, such as black and white. Place the piece of cloth within reach of the child so that she or he can grasp it if interested. These pieces of cloth are very attractive to babies and easy for them to handle. They will gradually find more ways of manipulating the cloth, clutching it, putting it in their mouth and passing it from one hand to the other.

Hanging mobile

Age: 0-12 months



Specific skills targeted: encourages development of vision and the ability to focus on moving objects and follow them with the eyes, perception of colours and depth and calm and alert observation.

Materials for making the mobile: black crayon, white paper, glue and yarn

Method: draw simple, contrasting black and white images and hang them over the child's cot or play area.

Activity: When placed in the cot or changing area, the child is able to see the mobile. Babies prefer this type of image in their first months, as they are sensitive to contrast.

My reflection

Age: 4-12 months



Specific skills targeted: visual stimulus, self-recognition. Observation, hand-eye coordination, communication.

Materials: small mirror or lightweight metal plate.

Activity: offer the child the mirror or plate so that he can see his reflection or that of different parts of his body. This allows the child to explore and experiment with body language and recognise his reflection.

Musical bottle

Age: from birth



Specific skills targeted: Coordination, rhythm and recognition of sounds and sound levels, concentration and abstraction.

Materials:

- Plastic bottle, approx 200 cl size.
- Pebbles
- Glue

Instructions: wash and dry the bottle, fill it a quarter full with pebbles and fix the lid with glue (so that there is no risk of the baby opening it, since infants tend to put everything into their mouths)

Activity: The bottle makes a noise when shaken. With babies aged 0-6 months, it can be used to stimulate

them to search for the source of the sound. Between 6 and 12 months, the baby can be offered the bottle to handle and experiment with, without direction. From 12 months on, activities can be introduced, showing how the bottle can be struck with varying rhythms and intensity..

Musical spoons!

Age: 6-12 months



Specific skills targeted: Coordination, rhythm and recognition of different sounds, materials and changes in intensity.

Materials: spoons, old pots and pans.

Activity: Give these implements to the child, so that they can make noises and experiment with the different sounds created. The adult can either leave the child to explore freely or may guide by example, producing sounds of varying rhythms and intensity and encouraging the child to do the same.

Guitar

Age: 6-12 months



Specific skills targeted: Coordination, rhythm and changing intensity.

Materials: a jelly mould and rubber bands.

The rubber bands are stretched tightly around the mould (see picture). The child can make noises with it as if it were a guitar. *This activity should be supervised by an adult, as the rubber bands can easily come adrift and are unsuitable for a child to place in her mouth.*

Treasure chest

Age: 9-12 months



Specific skills targeted: Sensory stimulation, exploration; development of precise movements; fine motor skills; autonomous observation of objects.

Materials: A cardboard box filled with everyday objects (plastic bottle, piece of cloth, plastic cup, roll of toilet paper, wooden spoon, hairbrush, small box, etc).

Activity: This should ideally be used once the child is able to sit by themselves and hold objects with both hands.

The game consists of placing a basket, not too deep and full of everyday objects, within reach of the baby. The only requirement is that the objects should be too big for the child to swallow, and should not be dangerous. The child then picks out objects and will use all her senses with each one of them, moving them, finding out whether they make a noise, what they feel like and how hard they are. She will put them in her mouth, smell them and examine them.



Peek-a-boo!

Age: 4-12 months

Specific skills targeted: coordination and awareness of the presence/absence of people and things. Playful interaction with a significant adult.

Materials: Hands, or a piece of cloth.

Activity: This game involves another person. The parent or carer can cover themselves with the piece of cloth, playing at 'where's she gone?' and 'here she is!' and encouraging the child to do the same.

It's gone!



Age: 3-12 months

Specific skills targeted: Prediction of events, cognitive thinking skills, permanence and stability of objects, playful interaction with a significant adult.

Materials:

- Everyday objects
- Blanket, towel or cloth

Activity: Various items are gathered and placed where the child is unable to see them. The adult sits in front of the child, picks up an object and shows it to the child. Holding the object close to his or her face, the adult covers the toy with a cloth and talks to the child to hold her attention. While the child watches, the adult covers the toy with a cloth and says 'It's gone!', then waits a few seconds before uncovering it and saying 'Here it is!' The game is repeated with the remaining objects. If the child becomes anxious when the toy disappears, the adult hides it more slowly so that the child can see what the adult is doing. The toy should not be left covered for too long.

Through the tunnel



Age: 9-12 months (as soon as they start to crawl)

Specific skills targeted: cognitive/thinking skills; perception of depth; problem-solving. Playful interaction with a significant adult.

Materials:

- Three cardboard boxes, big enough for the child to crawl through
- Scissors
- Sticky tape

Activity: Once the baby starts to move around, a tunnel can be made for the child to crawl through. He will discover new ways of moving and all that is needed is a large cardboard box.

Cut the flaps off the three large boxes, cut out a few holes to let air in and join the boxes with sticky tape so that they form a tunnel. Show the child, bringing her close to one end of the tunnel. The adult goes to the other end and calls the child, so that she crawls through the tunnel. Repeat the game several times, allowing the child to investigate the inside of the tunnel and have fun with it.

From 1 to 3 years old



Characteristics of this stage

Growing independence From their first year of age, children are more independent and are mastered the skill of standing; they can move around and start to say their first words. They are able to move their whole body and begin to co-ordinate their movements. As their motor skills and control over their body develop, so do their opportunities for play and learning. In addition to the activities outlined below, it is important that children have a safe space for free- and self-directed play. Ideally, equipment should be available and the supervising adult should be present, taking an interest and supporting the child, putting limits in place (mediating in conflicts or making sure that toys are being used safely) but not interfering in, or leading the activity.

Language During this period, language abilities improve rapidly. A child will normally be able to say one word at 12 months and approximately 50 at 18 months. It is a period in which children consolidate the skills they have already learnt.

Boundaries Children will also be testing boundaries and exploring their independence. They practise using “no”. They will say no often, which is to be expected and is a good thing. It shows that they are trying to assert their independence and autonomy. Play can be an opportunity to practise this and allows them to put their foot down or pursue their own ideas in a safe environment.

Types of play

Associative play Children are now ready for social interaction and are able to follow instructions as well as the routines with which they are familiar. They are able to relate to children they know and spend less time engaged in individual play. They can take turns in an activity. This is a type of play which builds social relationships and helps to develop their self-control.

New appreciation of objects At this age, children are really interested in fetching and carrying objects. They build towers and knock them down, they like containers and boxes. They try to put objects in and see if they can fit them inside and shut the lid. They are very interested in balloons and balls and in the games that can be played with them. They also like banging drums, striking them with great enthusiasm. They should be given the opportunities and materials to allow them to develop their motor skills.

Water At 18 months children discover water, splashing when they wash their hands, filling containers with water and emptying them. They enjoy the feel and sensation of playing with water. This is the time to offer children containers so that they can transfer liquids which will enable them to explore such stimulating concepts as how to measure quantity and the properties of liquids.

Reading This is also a suitable age to include reading more often into children’s routines; at this age they start to turn the pages in books. It is time to start reading stories; at first they will simply listen to the sound of the words you read to them and won’t yet fully understand the meaning.

Equipment recommended for a free play area:

- blocks of wood for stacking and building

- baskets filled with shells, stones, sticks, pieces of material (to choose, group, mix and rearrange)
- balls
- Play house. It is strongly recommended that children have an area where they feel cosy and protected. They like to be inside tents, between chairs with some fabric draped over the top.
- Pieces of string
- drawing and colouring supplies

Recommended activities

Tube talking



Age: 12-24 months

Specific skills targeted: Communication. Language development. Listening skills

Equipment:

1. Toilet roll or kitchen roll tubes
- Colour pencils

Activity: Decorate the cardboard tubes in an appealing way, letting the children help. Put the tube to your mouth and talk to the children. The sound will be amplified.

Give the tubes to the children so that they can experiment and copy you. Encourage them to talk through the tube. You could try making different sounds through the tube: animal noises, nature sounds, musical instruments, etc.

Catch the firefly



Age: From one year

Specific skills targeted: Cause and effect, movement and co-ordination. Gross motor skills.

Equipment:

- Paper
- Scissors
- Torch
- Sellotape
- Dark room

Activity: When a child is able to move around more easily, she will love catching games. This game involves her trying to catch the “firefly” on the wall.

Cut out a hole from piece of cardboard in the shape of an insect such as a firefly, making it fairly small so that it can fit into the lens of the torch. Stick the silhouette to the torch with sellotape. Take the children to a dark room. Then turn on the torch, pointing it at a wall. Move the light slowly along the wall to catch the children’s attention. Tell them to catch the firefly moving along the wall. Move the light around, bringing it closer and further from the children as they try to catch it.

Recognise and sort

Age: 12-18 months



Specific skills targeted: Exploration, hand-eye co-ordination. Learning to recognise and sort size differences.
Equipment: Assorted objects (containers, boxes) which can fit into each other.
Activity: Put a few plastic containers of different sizes next to the child and encourage her to put some inside others. Explain what is happening and what they have managed to do. "You've put the small box inside the middle-sized one! Which is biggest?"

Painting sponge



Specific skills targeted: Mobility, creativity, co-ordination

Equipment: Container filled with water and a sponge

Activity: Offer the child a bowl filled with water and a sponge. First show her how to soak the sponge and then squeeze it. Wipe it over a surface, pretending that you are painting. Then let the child try as many times as she likes.

Body part recognition



Age: from one year

Specific skills targeted: Self-awareness, co-ordination and vocabulary
Activity: Name a body part and ask the children to touch that part of their body. You could also sing:
Head, shoulders, knees and toes.
Head, shoulders, knees and toes.
And eyes and ears and mouth and nose. Head, shoulders, knees and toes, knees and toes.

Colour instructions



Age: from 2 years
Specific skills targeted: Recognising colours and following instructions.
Activity: Sit the children in a circle and give them colour-related instructions. For example:
-If you are wearing something red - stand up.
-If you are wearing something blue – touch your nose.
- If you are wearing yellow today – sing a song.
- If you are wearing something green – turn around.

Pretend wings



Age: from 2 years.
Specific skills targeted: handedness, co-ordination, self-awareness.

Equipment: Music and a tambourine (or something that makes a similar sound).

Activity: Spread the children around the whole play-area. Tell them that they are butterflies and have one broken wing. "THE BUTTERFLIES HAVE HAD AN ACCIDENT. THEY HAVE BROKEN A WING!" When the music is on, they should start to dance, moving only one arm up and down. At the sound of the tambourine, they swap arms and carry on dancing. And so on... each time you sound the tambourine, they swap arms.

Little Plane



Age: from 2 years.
Specific skills targeted: Co-ordination of movements, development of the imagination and balance. Activity: Spread the children around the play-area with their arms out and their feet together, in the shape of a plane. "EVERYBODY IN PLANE POSITION!" Tell them to pretend to take off and fly, trying to keep their balance at all times. "STOP!" Tell them that they have stopped because they've entered a cloud. Then carry on flying because they are out of the clouds. Finally, when you tell them to fly "HIGHER!" they stand on tiptoes and carry on with the game.

Kangaroos



Age: from 2 years
Specific skills targeted: Balance and co-ordination, respecting limits.
Equipment: Chalk or string.

Activity: Make a dotted line with a piece of chalk or some string in the play-area. The children form a queue, one behind the other. They should to walk, one by one, stepping on the line and keeping their balance. "WE CAN'T STEP OFF THE LINE!" Once they reach the end of one part of the line, they should jump with their feet together onto the next one. When they have reached the end, they should jump back to the start like kangaroos, jumping from one side of the line to the other.

Talking hands



Age: from 2 years.
Specific skills targeted: Dexterity. Moving one part of the body and discovering their own expressiveness.
Equipment: Pictures of different objects.

Activity: Sit the children in a semi-circle at one end of the play-area. Place on the table pictures of a number of different objects, including: a pair of scissors, a ball, a staircase, a pencil, a cup and a flute. Show them to the children and ask them to use their hands to represent the object that you are showing them and then copy its movement. "JUST WITH YOUR HANDS!" End the game when they have used their hands to make all the objects.

Musical Statues



Age: from 2 years.

Specific skills targeted: Balance and rhythm, body awareness and creativity.

Equipment: Music

Activity: The children dance to the music with their movements reflecting the feel of the music (fast, slow, gentle, animated). When the music stops, the children must freeze until it starts again.

From 3 to 5 years old



Characteristics

Playing with others At three years old, children are more sociable and their style of play is increasingly affected by the presence of other children; they will watch to see how older children act so they can copy them. It is a stage in which fantasy and reality come together in the minds of children. In their play, they will act out scenes from everyday life, adding in elements of fantasy.

Emotions They are able to understand and identify different emotions and can recognise when others are happy, sad or angry.

Independence Children at this age are normally able to eat without help and control sphincters during the day. They will increasingly be able to help with small tasks and will be able to dress, wash and dry themselves independently.

Motor skills Children are more and more able to move about, can walk up and down stairs and have generally good control over their bodies. Fine motor skills are also well developed and they will choose to draw things (circles, lines etc.) although they prefer to explore the use of colours.

Learning At this stage children can recognize and name colours, sort objects according to size, shape, colour, use, recognise quantities and count to 5. They often ask the meaning of words they don't understand and can tell you about something that has happened or what they see in a picture. They can also learn a song and know if they are a boy or a girl.

Types of Games

Symbolic Play Beginning at the age of 3 is when symbolic play begins. As it progresses in symbolization, the game expands with more nuances. They can "pretend like" they're taking care of a doll, feeding it, hugging it, etc. It's a very important and special moment. It's when fantasy and creativity are strengthened. This leap is very important since this type of play gives them the opportunity to express their fears and worries.

During the symbolic-play stage, children like to dress up and pretend to be another person. In this way they build the capacity to imagine what someone else might be feeling or thinking, and this is fundamental for the development of empathy. They can also "make believe" that they have overcome a difficult situation. This helps them to develop greater confidence in themselves.

Social Play At 3 they also begin social play (which means that until then they can play next to someone but not with another child), but it is not until 5 that it has finished being defined and they find it easy to share games and play with friends. At this age they can begin to participate in collective games, but it's very important that the rules and limits are very clear and well detailed.

Simple Materials They don't need many things, only unsophisticated toys, things that pique their imagination, which can serve to create fantastic games. If we offer them a piece of wood, a box, a few pieces of clothing... they can create great things.

Recommended Activities



Giant Bubbles with a Rope

Specific Abilities Developed: Cause and effect, Exploration, Social Interaction

Materials:

- Bottle of dishwashing detergent

- Hair gel or hairspray (this is so the bubbles turn out better, but it's not essential)
- Container with water
- 2 sticks
- 1 thin rope or piece of yarn

Activity:

Mix 9 parts water, 2 parts hairspray or hair gel, and 1/2 part liquid soap. Let the mixture sit for approximately an hour. Construct the bubble blower (with the sticks and the yarn). Cut the string about three times longer than the length of one of the sticks. With this string make a hoop (the lower string a little bit longer than the lower one, as shown in the photo below).

Finally, dip the hoop in the soapy mixture and ready! You can start making giant soap bubbles.

Walking Animals



Specific Abilities Developed: Dramatic representation, Expression of Emotions, Development of simple movements, Social skills.

Materials:

Drawings or cut-outs of animals: for example ducks, crabs, spiders, kangaroos, elephants, caterpillars, rabbits, seals, snakes, etc.

Activity:

The children are placed in a circle and they are shown different animals. After showing one, everyone imitates that animal with their body, moving and making noise. The adult can participate by explaining how ducks walk, telling them that crabs walk sideways, that the kangaroo jumps, that the elephant sways, that the caterpillar arches its body and extends it forward, that the rabbit hops, that the seal glides, that the snake slithers, etc.

Box Car



Specific Abilities Developed: Body awareness. Creativity and imagination. Development of simple and precise movements. Spatial relations. Social skills

Materials:

- Large box, approximately half the size of the child.
- Scissors
- Adhesive tape
- Markers, crayons, paint, stickers or other decorative materials.
- Book or cutouts of cars

Activity: The children are placed in a circle and they are told a story about a car (once upon a time there was a car that wanted to go very far and very fast...) at the same time they are shown a picture of a car.

Later build cars: first remove the top and bottom lids of the box. If necessary, place tape on the edges and corners to soften and strengthen them.

The children decorate the exterior of the box so that it looks like a car or truck. When the car is finished, invite the children to drive it. A car for every 3 children is recommended. At this age they are capable of taking turns.

You can also make "streets" with masking tape on the ground, so that when the activity has finished they can be removed without a problem.

Every Lamb Has Its Partner



Specific Abilities Developed: Sorting abilities. Cognitive thought skills. Development of language and vocabulary. Correspondence Skills.

Materials:

- Objects with something in common, for example pencil and paper, shoe and sock, fork and Plate, soap and towel, toothpaste, comb and hair clip, etc.
- Table or floor

Activity:

Teach the children to pair the objects.

1. Collect different objects that can be pair but that aren't the same.
2. Separate the objects and make two piles.
3. Put the first pile on the floor or on the table, in front of the children.
4. Take one of the objects from the other pile and show it to the children.
5. Ask them to find the one that makes a pair with that object. Put the pair aside and take another object.
6. Repeat the game until all the objects are paired. Comment on which objects go together and which ones don't and why.

Animal Parts



Specific Abilities Developed: Observation abilities, Problem resolution, Classification. Fine motor skills.

Materials:

- Images of animals taken from magazines
- Scissors
- Glue
- Sheets of Paper
- Table or the ground

Activity: The make pairs with the halves from different animals, or have fun creating mismatched animals.

1. Cut out the images of various animals.
2. Cut the images in half, separating the front part from the tail.
3. Put the front parts on the floor or on the table in front of the child.
4. Take out the rear parts and get the child to pair it with the corresponding front half.
5. Stick the completed animals on a sheet.
6. You can also create mismatched animals and play putting together parts that don't belong together.

Dward, Giant, Rabbit!



Specific Abilities Developed: Body awareness. Development of simple and precise movements. Spatial relations.

Materials:

- Large Surface

Activity: the children listen carefully to a few simple instructions and continue to follow them.

1. The children are grouped in a circle on the large surface that is free of obstructions so that the children have sufficient space.

2. The children begin walking in a circle, all in the same direction, and they are asked to do one of the following things: hop like a rabbit, take big steps like a giant while stretching their hands to the ceiling, or walk hunched over like a dwarf.

3. Continue alternating instructions and the person who calls them out does the same.

4. Directions continue to be given, each time more quickly. When they tire, return to the initial speed.

5. You can also play again by adding instructions, for example ones like dance, rotate, applaud, open and close your legs while jumping, etc.

TABLE OF GAMES AND AGE

AGE	TYPE OF GAME
3-9 months	Plays and explores their own body and that of the main carer.
9-12 months	Plays and explores objects; searches, hits, pulls... explores corners and furniture.
12-18 months	Tries to use objects and toys according to their properties and more evident functions.
18-24 months	Is able to combine two or more toys into a simple game play.
24 to 36 months	Is able to increase the complexity of the games and the number of elements. Practices games of movement, staging and building.
3 to 5 years	Starts role playing, plays with other children, but in parallel (not "with them")
5 to 7 years	Social games, collective games with clear limits and rules. Creative ability and imagination. Greater logic and reasoning ability
8 to 12 years	Games with rules, development of language, memory, reasoning, attention and reflection. Games of collaboration, team building and personal development.

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