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Play-based family-centred psychomotor/psychosocial stimulation and the recovery of severely acutely malnourished children

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Play-based family-centered psychomotor/psychosocial stimulation and the recovery of severely acutely malnourished children

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Dedicated to my father Gemechu Abessa, Abbaa Takluu

For you said, “Do not let my son hear my death and miss his mission”.

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List of abbreviations

AIDS—Acquired Immunodeficiency Syndrome

ASQ:SE—Ages and Stages Questionnaires: Social-Emotional

BAZ—body-mass-index-for-age z score

FM—fine motor

GM—gross motor

HAZ—height-for-age z score

HIV—Human Immunodeficiency Virus

ICF—The International Classification of Functioning, Disability and Health

LA—language

MUAC—mid-upper-arm circumference

MUACZ—mid-upper-arm circumference z score

NRU—nutritional rehabilitation unit

PS—personal social

RUTF—ready-to-use-therapeutic food

SAM—severe acute malnutrition/ severely acutely malnourished

SD—standard deviation

SE—social-emotional

WAZ—weight-for-age z score

WHO—World Health Organization

WHZ—weight-for-height/ length z score

Abstract

Severe acute malnutrition (SAM) remains a great health challenge in low and middle income countries (LMICs). SAM has severe short-term and long-term consequences on growth and the development of children. To mitigate the effects of SAM, the World Health Organization (WHO) recommends combining psychosocial stimulation with dietary rehabilitation. There are challenges in implementing the recommendation in some low-income settings where even basic food for survival let alone balanced diet, remains scant. In such contexts, there is a scarcity of accurate data on the magnitude of the effect of SAM on the different dimensions of child development. Psychosocial intervention studies aimed at mitigating the developmental effects of SAM are not only sparse, but also have limitations in design and use of Western child development tools in non-Western settings without adaptation. No study has so far used a randomized controlled trial during and after hospitalization, because of a belief that it is unethical to give intervention to certain participants in the same hospital ward through randomization. Therefore, there is a lack of strong scientific evidence of the contributions of psychosocial stimulation for children with SAM. Due to a lack of culturally relevant child development assessment tools in such low-income settings, little is known about the accuracy and reliability of the Western tools used to assess the developmental impacts of the interventions. The primary goal of this thesis was therefore to expound the effects of play-based family-centered psychomotor/psychosocial stimulation in mitigating the deleterious effect of SAM on child development in a low-income context. To achieve this main goal, adapting a Western child development assessment tool to the local study setting and documenting the magnitude of SAM on the different domains of child development were respectively addressed as first and second prerequisite studies. Hence, the thesis documents three studies: the adaptation and standardization processes in making a Western child development screening tool culturally relevant for use in a non-Western setting (Study 1), determining the magnitude of developmental delay among SAM children of different ages so as to undertake an insightful intervention (Study 2), and examining the effect of psychomotor/psychosocial stimulation on development, linear growth and nutritional outcomes of SAM children (Study 3). The studies were conducted in Jimma Zone, South West

Ethiopia on children under six years of age. Study 1 was a three-phase process, conducted on healthy children in Jimma town: pilot survey, pilot feasibility and reliability, and final optimization and standardization on a large sample (n=1597; age= two days to six years). Of the 125 test items in the Denver II, 36 items (mostly in the personal-social domain) were adapted. The 90% age of milestones attainment on the adapted tool differ significantly from Denver II on 42 (33.6%) items (9 PS, 6 FM, 15 LA, and 12 GM). The test items in the adapted tool have good to excellent inter-rater and test retest reliabilities. Study 2 examined the magnitude of developmental delay among SAM children of different ages by comparing the developmental performances of 310 SAM children with that of age and 310 sex-matched non-malnourished healthy children (N=620, mean age=30.2, range=3-66 mo.). A more severe delay was observed on very young children on gross motor, followed by fine motor functions than on older children. Study 3 was a randomized controlled trial conducted on SAM children from different districts in Jimma Zone admitted to the Nutritional Rehabilitation Unit at Jimma University's Specialized Referral Teaching Hospital for medical and dietary treatment (N=339; mean± SD age = 27.4±15.1mo, range=6.1—65.7mo). The SAM children were randomly assigned to control (n=170) and intervention (n=169) groups. At the hospital, both groups received standard medical and nutritional treatment but the intervention group received an additional psychomotor/psychosocial stimulation in the form of play in a playroom alone or a playroom and playground furnished with play materials. Trained clinical nurses offered the stimulation to the child (psychomotor) in the presence of the child's caregiver. Caregivers were given education on childcare, feeding, and stimulation in addition to practical training on how to use play materials to stimulate the SAM child. After discharge from hospital, caregivers and significant others in family were involved. Through play, a child was engaged in activities that facilitate physical growth and mental, linguistic, social, and emotional development. The intervention continued at home through mediation by caregivers. Three home visits were made by intervention nurses to follow up each child. The child's linear growth, nutritional status, and developmental performances before the start of intervention, at discharge from hospital, and after six months of home follow-up were determined. The intervention group scored significantly higher during hospital follow-up in gross motor skills ($p<0.001$, effect size= 0.26 SD), and during home follow-up in fine motor skills (p=0.001, effect size=0.15 SD). The effect of the intervention, however, is small. The intervention had no significant effect on linear growth and nutritional outcomes. The hospital-based follow-up was shorter than the home-based follow-up. However, it was a period when the SAM children were provided with an adequate and balanced diet, and full-time attention and support from a caregiver. During the home-based follow-up, the SAM children had no access to an adequate and diversified diet. The duration of the follow-up predicted all developmental outcomes and indicated a possibility for a significant intervention effect if prolonged. The age and sex of child and baseline developmental performance level did not affect the outcomes of the intervention on all the examined domains of development. However, compared to the control, the intervention children who started receiving the stimulation with a better nutritional status as measured in weight-for-height or body mass-index-for-age improved better in wasting status (β=0.02, p=0.012), though this did not improve any of the developmental outcomes assessed. In short, the study shows play-based child-focused psychomotor activities and family-centered psychosocial stimulation activities that address the child's immediate social and physical environment can contribute in the developmental recovery of SAM children.

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CHAPTER 1: GENERAL INTRODUCTION

1.1. Aims of this work

Though there is a global decline in mortality of children under five (UN, 2012), malnutrition remains a major threat to millions of children. Many children are surviving the risks of malnutrition, but survivors suffer limitations in linear growth and behavioural development (J. Galler et al., 2010; J. R. Galler et al., 2012; Sally Grantham-McGregor, 1995; Martorell, 1997; Tofail et al., 2012), cognitive (Benton, 2008; Isaacs & Oates, 2008; Prado & Dewey, 2014) and motor (J. R. Galler, Ramsey, Salt, & Archer, 1987b) functions. 249.4 million (43%) children under five in low- and middle-income countries have been exposed to the deleterious effects of sub-optimal development due to malnutrition and poverty (Lu, Black, & Richter, 2016). Furthermore, malnutrition causes far-reaching damage, because it has transgenerational (Roseboom, Painter, Abeelen, Veenendaal, & Rooij, 2011) and multidimensional effects, and contributes to the loss of human capital (Victora et al., 2008). Among the different types of child malnutrition, severe acute malnutrition (SAM) in particular is a more serious threat to the survival and wellbeing of many children in low-income countries. Curbing its damaging multidimensional effects requires a more comprehensive child healthcare service that addresses health and nutrition interventions. Nevertheless, such services are lacking in poor countries, where they are needed most. For example, in Ethiopia, where many SAM children are admitted to hospital, they get only medical treatment and nutritional rehabilitation. Many of the children survive but continue to face life-long challenges due to reduced intellectual capacity arising from lowered cognitive and language development (Aboud & Yousafzai, 2015). To curb this problem, the World Health Organization (WHO) recommends supplementing psychosocial stimulation to the treatment of SAM (WHO, 1999, 2013; WHO/WFP, United Nations System Standing Committee on Nutrition, & The United Nations Children's Fund, 2007). However, very few studies (Sally Grantham-McGregor, Powell, Walker, Chang, & Fletcher, 1994; Sally Grantham-McGregor, Schofield, & Harris, 1983; Sally Grantham-McGregor, Schofield, & Powell, 1987; S.M Grantham-McGregor, Powell, Walker, & Himes, 1991; B. Nahar et al., 2009; Baitun Nahar, Hossain, Hamadani, Ahmed, Grantham-McGregor, & Persson, 2012) justify the recommendation, with limited evidence that psychomotor/psychosocial stimulation has the potential to reduce the negative effects of severe acute malnutrition[1]. A very recent systematic review of psychosocial stimulation studies on SAM children showed insufficient high-quality evidence to recommend the provision of psychosocial stimulation in children with SAM (Daniel et al., 2017). The review also emphasizes that the studies used developmental assessment tools that were not culturally validated or locally standardized, and that they have high risks of different types of biases. It identified the urgent need to conduct randomized controlled trials in order to produce stronger evidence.

This doctoral thesis reports three studies conducted in different phases. The first two studies are preconditions for the main study, which is addressed in the third phase. The thesis primarily aims to show the effects of psychomotor/psychosocial stimulation (psychomotor—working directly with the child; and psychosocial—working both with the child and his/her immediate social environment) on nutritional and developmental outcomes of SAM children of six months to six years of age during nutritional rehabilitation at hospital and at home after discharge from hospital, using a randomized controlled trial design. The fine motor, gross motor, language, personal-social and social-emotional development; height[2]-for-age, weight-for-age, weight-for-length/height or body-mass-index-for-age[3] Z-scores of SAM children were examined during in-patient treatment in hospital and six months after discharge from hospital. For a valid and reliable estimation of the developmental outcomes, the use of culturally relevant, simple and feasible tools to use on the SAM children who are weak, sick, and fragile was an essential precondition for the study. Therefore, the first phase study aimed to adapt and standardize a Western child development screening test for local children in order to make it culturally relevant and reliable for assessing the developmental performances of the local children. Having an insight into the magnitude of the developmental effect of SAM during its acute stage is essential in order to provide more focused interventions. Hence, the second phase study aims to examine the developmental performances of the SAM children in comparison with age- and gender-matched healthy children. The third phase

[1] 'Malnutrition', 'malnourished', and 'under-nourished' and 'under-nutrition' are used interchangeably.
[2] In this paper length and height, as well as weight-for-length and weight-for-height, are used interchangeably.
[3] Body-mass-index-for-age Z score was used for children whose age at time of measurement was greater than 60 mo.

study, as the main goal of the work of the dissertation, examines the effect of psychomotor/psychosocial stimulation on development, linear growth and nutritional outcomes of SAM children during hospital-based and home-based treatment and rehabilitation.

1.2. Malnutrition: definition and types, causes and burdens

1.2.1. What is malnutrition?

Nutrition refers to the food and the process by which a living organism assimilates food and uses it for growth and replacement of tissue (American Heritage Dictionary of the English Language, 2016). To keep us alive and healthy, the food we eat undergoes the following processes: ingestion, digestion, absorption, transportation, assimilation, and excretion. A condition that disrupts these normal processes and disturbs the dietary requirements of the body can lead to malnutrition. Malnutrition is the condition that develops when the body does not get the right amount of the vitamins, minerals, and other nutrients it needs to maintain healthy tissue and organ function (Medical Dictionary, 2008). It refers to both undernutrition (not getting enough nutrients), and over-nutrition (getting more nutrients than the body needs) (UNICEF, 2013) resulting from an inadequate or unbalanced diet, digestive difficulties, absorption problems or other medical conditions (Nordqvist, 2017). In the context of the present work, the term malnutrition is used to refer to under-nutrition unless specifically mentioned that it refers to over-nutrition.

In order to function, the human body needs a regular supply of energy and nutrients. Both macronutrients (carbohydrates, proteins and fats) and micronutrients (minerals and vitamins) are essential for growth, development and healthy life. Our body requires macronutrients in large amounts (Nordqvist, 2017). A common macronutrient deficiency arising when children do not consume an adequate amount of carbohydrates, fats and proteins is a *protein-energy malnutrition* (World Food Program, 2018), which usually manifests in the form of marasmus, kwashiorkor or marasmic-kwashiorkor. Micronutrients are required in small amounts by our body. Micronutrient malnutrition includes deficiencies in vitamins and minerals. Of the world population of 7 billion, about 2 billion suffer from micronutrient malnutrition (International Food Policy Research Institute, 2016).

During malnutrition, muscle mass is lost because the body starts to use muscle tissue for energy. Body fat and protein in muscles begin to break down, the metabolism begins to slow down, thermal regulation is disrupted, the immune system is weakened and kidney function is impaired. These actions lead to fatigue, body wasting, renal failure, and exposure to different infectious diseases (França, et al., 2009; Klein, 2012). Child malnutrition can be of the acute or chronic type. Chronic malnutrition is the result of a long-term, cumulative effect observed during the course of a life-time in the form of stunted growth, whereas acute malnutrition is the recent and sudden loss of body weight observed in the form of wasted muscles.

Acute malnutrition implies a significant weight and muscle mass loss resulting from a recent dietary deficit and related complications. Depending on the degree of its severity, acute malnutrition can be moderate or severe. Severe acute malnutrition (SAM) is an extreme form of undernutrition reflected in terms of very low weight-for-height and very severe muscle wasting, or nutritional oedema that is characterized by swollen feet, face and limbs (UNICEF, 2015).

1.2.2. Causes of malnutrition

Hunger is the leading cause of malnutrition. According to the 2015 report of The Food and Agriculture Organization of the United Nations, one in nine (about 795 million) of the 7.3 billon world population is facing chronic hunger. Around one million children die every year from hunger-related causes. The highest prevalence of hunger (780 million) is in the developing world (FAO, IFAD, & WFP, 2015). This hunger problem co-exists with lower maternal education and poor awareness about childcare and dietary diversity. Undernutrition is also caused by frequent illness, inappropriate feeding and care practices (Imdad, Yakoob, & Bhutta, 2011), poor-quality health and care environments and behaviours (WHO, 2006b), which are shaped in part by political instability, poor economic development, conflict, inequality, and some impacts of globalization (International Food Policy Research Institute, 2016; UNICEF, 2013). In 1990, UNICEF developed a conceptual framework which classified causes of malnutrition into three: immediate, underlying, and basic (Lidan, 2014).

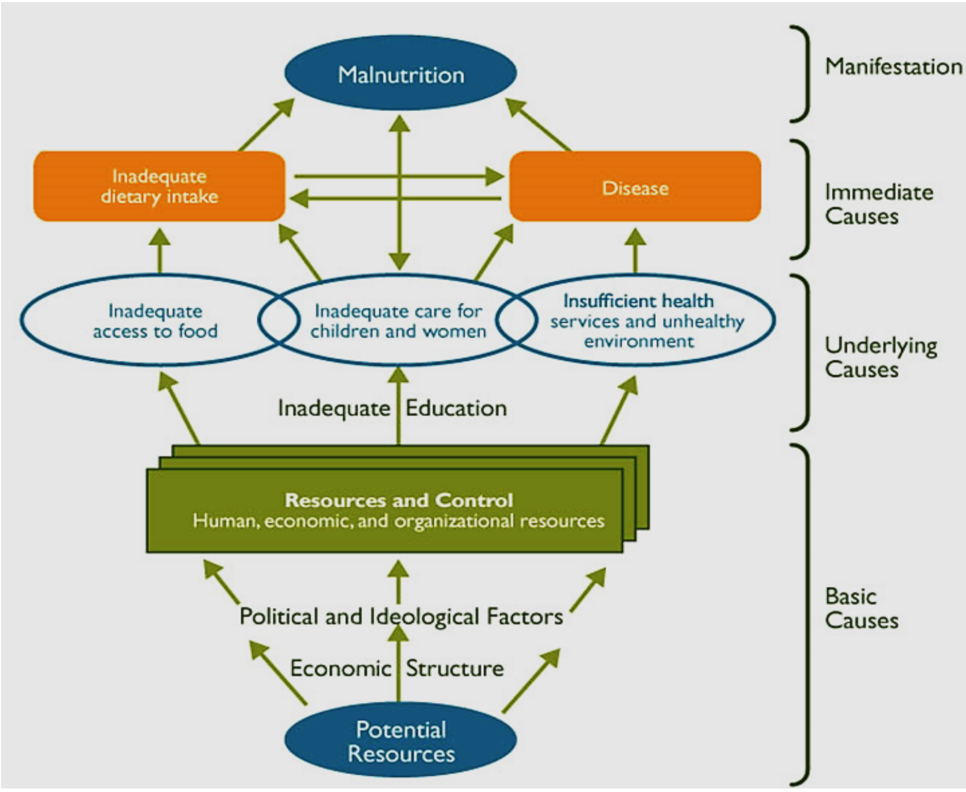

Figure 1.1. UNICEF's conceptual framework on the causes of malnutrition (source: Lidan, 2014)

The framework shows that the causes of malnutrition are multifaceted, and that effective action requires addressing these complex factors in a multi-sectoral approach.

1.2.3. Magnitude of child malnutrition: global and local pictures

The most vulnerable group for malnutrition are children. In 2017, globally 50.5 million children under-five were wasted, 16.4 million of which were severely wasted. In Africa, 13.8 million were wasted, 4 million of which were severely wasted. In the same year, 150.8 million and 38.3 million children under five respectively were stunted and overweight worldwide (UNICEF, WHO, & World Bank, 2018). One in three stunted children lived in Sub-Saharan Africa (International Food Policy Research Institute, 2016). Child undernutrition is more common in low- and middle-income countries, where poverty remains a chronic problem. Half of all wasted children lived in South Asia and one quarter lived in sub-Saharan Africa (UNICEF, 2017). Though undernutrition is generally declining worldwide, the rate of stunting is not declining fast, particularly in Africa (Food and Agriculture Organization of the United Nations, 2017). An estimate in 2016 showed that 44.1 million (38%) of children under five in Sub-Saharan Africa are stunted, and 115.5 million (81%) are at risk of sub-optimal development (Lu et al., 2016).

Ethiopia has the highest rate of malnutrition in Sub-Saharan Africa (Save The Children UK, 2009). Malnutrition is a long-term and year-round household problem found across all Ethiopian regions (Chamois, Golden, & Grellety, 2007), which usually accompanies periodic drought and concomitant famine. There has been considerable progress in child nutrition in Ethiopia from 2000 to 2016. A report showed a decline in under-five child malnutrition from 58, 41 and 12 percent in 2000 to 38, 24 and 10 percent in 2016 in stunting, underweightness and wasting respectively (Central Statistical Agency [Ethiopia], 2016). However, the situation of child malnutrition in our present study area seems not to have improved much. Data collected 22 years ago from 669 randomly selected children under five living in a part of the present study site (Jimma town) showed about half (48%) of the children to be malnourished, with 36%, 9% and 36% being underweight, wasted and stunted respectively (Getaneh, Assefa, & Tadesse, 1998). A study was conducted later from March - February 2009 on 2410 children under five around the Gilgel Gibe Hydroelectric Dam (about 65 kilometres from Jimma Town). This study, which covers areas included in the present study, showed 14 years later that 40.4% of the children were stunted (height-for-age Z score <−2SD) and 34.2% were underweight (Deribew et al., 2010).

1.3. Effects of malnutrition on children

Malnutrition impairs general health, growth and development in children. It affects children physically, mentally, and emotionally. Long-term effects are seen in the form of attention deficit disorder, impaired school performance, decreased IQ scores, memory deficiency, learning disabilities, reduced social skills, reduced language development, and reduced problem-solving abilities. Malnutrition may happen at a prenatal or a postnatal stage of a child's development. In utero, it affects the placental-foetal development and causes neurological disorders (Diop, Millogo, Obot, Thiam, & Tylleskar, 2006), intrauterine growth retardation (Muthayya et al., 2006), congenital disorders, sensory impairments, severe infectious diseases, and atypical developmental disorders. Children facing maternal undernutrition during pregnancy are exposed to chronic health problems (Rooij, Wouters, Yonker, Painter, & Roseboom, 2010; Roseboom et al., 2011; WHO, 2003), poor growth, and impaired developmental outcomes (Abeelen et al., 2012; Barker & Clark, 1997; Belkacemi, Nelson, Desai, & Ross, 2010; Martorell, 1997; Wu, Bazer, Cudd, Meininger, & Spencer, 2004). During early lives of the postnatal stage, malnutrition affects different dimensions of child development (Benton, 2008; J. R. Galler, Ramsey, Salt, & Archer, 1987a; Janina R. Galler et al., 1987b; Hoorweg & Stanfield, 1976; Nwuga, 1977). In a lifespan longitudinal cohort study with a follow-up period of over forty-years , the neuropsychological profiles of Barbadian adults who had experienced an episode of moderate to severe protein-energy malnutrition confined to the first year of life were compared with that of a healthy community comparison group. The study showed that the group with malnutrition history were lower in measures of cognitive flexibility and concept formation, as well as initiation, verbal fluency, working memory, processing speed, and visuospatial integration (Waber et al., 2014). Surprisingly, such a finding was obtained from individuals who had a normal birth weight, were nutritionally rehabilitated, remained in good health throughout childhood, and achieved a complete catch-up in their physical growth by the end of adolescence. It has also been shown that malnutrition is a threat to the healthy development of the brain (Alamy & A.Bengelloun, 2012; Prado & Dewey, 2014). Children malnourished early in life start schooling with cognitive disadvantages compared to those that were not malnourished (Sanchez, 2009). As a result, they face learning difficulties and impaired achievement, and do poorly in cognitive and educational outcomes (Food and Agriculture Organization of the United Nations, 2017). Malnourished children lack energy and become less curious, less playful, and communicate less with the people around them (WHO, 2006a, 2013). This in turn impairs their physical, mental, cognitive, emotional, and social development (J. Galler et al., 2010; J. R. Galler, Ramsey, Morley, Archer, & Salt, 1990; Sally Grantham-McGregor, 1995; Martorell, 1997). Particularly in SAM children, malnutrition compromises immunity and makes them more susceptible to diseases such as diarrhoea and pneumonia. Hence, treatment of SAM should include helping the malnourished child to regain energy, strength, good health, and engage in interactions. Effective intervention during the acute stage requires a better understanding of the SAM child's abilities and functioning. This requires determining the magnitude of the effect of SAM at its acute stage on the different domains of child development among children of different ages. Yet, no such studies have been documented to date.

1.4. Measuring the effects of malnutrition

Malnutrition impairs both growth and development in children. Anthropometric measurements are often used to determine a child's *growth status*. The latter reflects a child's *nutritional status*. The growth status of a child is a quantitative measure of his/her body size in terms of total length or height, weight, muscle mass, head size and waist circumference. Body height/length and weight are measures that are used often to determine a child's growth status. A child may be too short for his/her age (stunted), or have too low weight for his/her age (underweight) or be both stunted and underweight. A child may be underweight because he/she is thinner than normal (wasted) or shorter (stunted) and thinner (wasted) than normal. By taking sex, age, or height into account, the outcomes are interpreted in comparison with a standard reference population after transforming into Z-scores using the WHO's Anthro or AnthroPlus software (WHO, 2011). These scores show both the long-term cumulative effects of nutritional deprivation and current nutritional condition of a child. A length, or height-for-age Z-score (HAZ[4]) shows how short or tall a child is compared to the median of the standard population. This is a measure of the cumulative effect of nutrition deficiency since and before birth. A weight-for-age-Z-score (WAZ) shows a combination of the current or recent weight status related to the short-term

[4] HAZ refers to both length-for-age-Z-score and height-for-age-Z-score

influence of acute undernutrition, and the weight status in relation to accumulated long-term influence on linear growth (weight-for-length/height-Z-score, or WHZ[5]). A Z-score between minus two and minus three SD defines moderate, and less than minus three SD shows severe undernutrition. HAZ <-2 SD shows stunting; WHZ <-2 SD shows wasting or thinness; WAZ <-2 SD shows weight loss (underweight) due to acute and or chronic undernutrition, and underweightness due to wasting (CDC, & WFP, 2004).

The developmental status of a child is an estimate of a child's physical, cognitive, emotional, language, and social skills. Child development is a biological, psychological, and emotional change that a child undergoes from birth to adolescence. It is the result of a child's interactions within a given socio-cultural context. Child development is therefore affected by the socio-cultural context in which the child is reared (Groark, McCarthy, & Kirk, 2014). This means that both physical and social environments in which interactions take place are crucial determinants of child development. For meaningful interactions that enhance child development, cultural tools and social experiences are essential cornerstones. When assessing child development, these contextual factors should be taken into account. This is because children of different socio-cultural contexts do not attain milestones at the same ages (Winskel, Salehuddin, & Stanbury, 2013). Milestones may be attained more quickly or slowly depending on the child's access to a developmentally stimulating environment and services: the nature, quality, variety, and intensity of developmentally stimulating activities and practices; the availability, variety and meaningfulness of socio-cultural tools (traditional and technological) and socio-cultural practices that enhance child development. The child's development is influenced by such variations in socio-cultural tools, values, and beliefs on child care practices. When tools created in a socio-cultural context other than that of the child are used to determine his/her development, biased expectations are imposed. Developmental profiles generated using such tools are inaccurate and not reliable. Hence, the tools for assessing child development need to be aligned with cultural and contextual factors. Unlike the more objective scores generated through anthropometric tools, which function independently of socio-cultural environments, developmental assessment tools are dependent on socio-

[5] WHZ refers to both weight-for-length-Z-score and weight-for-height Z-score

cultural environments. Unless carefully used, they often generate less objective and biased scores; they are often open to subjectivity, which poses the question of the validity and reliability of such tools.

Hence, obtaining a reliable estimate of the developmental profiles of children requires either developing culturally relevant tools or modifying those developed in other cultures in order to make them relevant to the specific context in which the child is brought up (Fernald, Kariger, Engle, & Raikes, 2009; Klein, 2012). The reliability of such tools also needs to be determined and reported. In many low-, and middle-income countries, there are neither indigenous nor properly adapted child development tools for use. As a result, there is little accurate data on child development in such countries. Researchers have estimated poor development from the prevalence of early childhood stunting (Victora et al., 2008) and the number of people living in absolute poverty (Engle et al., 2007; Sally Grantham-McGregor et al., 2007; Lu et al., 2016; Susan P Walker et al., 2007). This makes it difficult to have accurate information about the developmental effect of malnutrition in general, and that of the severe acute malnutrition in particular. The present work addresses this gap through a proper adaptation of two child development *screening tools* originally developed in Western socio-cultural contexts for use in the present study setting. The adaptation processes of only one of the tools is presented in this thesis. Moreover, as the focus is on severe acute malnutrition, issues related to chronic malnutrition are not discussed in this work.

1.5. Treating severe acute malnutrition

The immediate cause of SAM is the deficiency in nutrients that the body needs for a normal metabolism. Hence, the primary target for intervention is nutritional rehabilitation. Dietary deficit in poor settings usually co-exists with a number of infectious diseases such as malaria, diarrhoea, measles, and HIV/AIDS. The management of SAM, therefore, should combine medical treatment with nutritional rehabilitation. SAM weakens the muscles of children and limits their interaction with physical and social environments. In doing so, it also hampers children’s cognitive, physical, emotional, and social development. Hence, effective treatment should address the illnesses, the dietary deficits, and the limitations imposed due to both conditions. Dietary treatment is crucial to reverse a further escalation of the severe consequences of malnutrition, reducing morbidity and improving growth of malnourished children. Developmental stimulations are essential to enhance the cognitive, motor, language, and social-emotional development of children. Therefore, it seems that activities that enhance motor and brain functions, language, emotional and social development contribute to the treatment of SAM children. A systematic review of studies that have examined the effect of interventions combining a child development component with a nutritional one has shown that nutritional interventions usually benefited nutritional status and sometimes benefited child development. Stimulation consistently benefited child development. There was little evidence of synergistic interaction between nutrition and stimulation on child development (Sally Grantham-Mcgregor, Fernald, Kagawa, & Walker, 2013). The review, however, included data other than malnutrition from studies on children from poor communities (Aboud & Akhter, 2011; DP et al., 1981; Vazir et al., 2013).

Interventions that combine medical treatment, dietary rehabilitation, and psychosocial stimulation have been acknowledged to have the potential to reverse or minimize the deleterious effects of severe acute malnutrition. So far however, no study result in this respect has been based on research with a randomized controlled trial design. As a result, there is a lack of high-quality research evidence to justify the contribution of psychosocial stimulation during the in-patient and out-patient treatment of children with SAM.

1.5.1. Medical and nutritional rehabilitation

According to the protocol recommended by the World Health Organization (WHO, 1999), SAM children are treated first as in-patients and then as out-patients. They are admitted to hospital as in-patients for a shorter period of stay, and discharged to be followed as out-patients. On admission to hospital, SAM children usually have serious illnesses and complications. They need intensive medical care and supervised dietary rehabilitation. This treatment is carried out in three phases. The first is an *initial treatment phase,* where life-threatening problems are identified and treated in a hospital or a residential care facility.

Specific deficiencies of the SAM child are corrected, metabolic abnormalities are reversed and feeding is begun. The second is the *rehabilitation phase* of intensive feeding aimed at recovering most of the weight lost. The SAM child is given fortified foods that are high in calories and protein. The WHO protocol also recommends intensive emotional and physical stimulation to be given to the SAM child, and a caregiver [6] to be trained to continue the stimulation at home while preparations are made for the discharge of the child. The third is the *follow-up phase,* when the child and the child's family are followed to prevent relapse and to assure the continued physical, mental, and emotional development of the child (WHO, 1999). This thesis examines the effect of integrating psychomotor/psychosocial stimulation in the treatment of SAM children on linear growth, nutritional and developmental outcomes on SAM children in the Jimma Zone, South West Ethiopia.

1.5.2. Psychomotor/ Psychosocial stimulation

Psychosocial stimulation is an educational effort to develop cognitive, physical, and motor skills, as well as the social-emotional abilities of children. It may benefit all children in general, and the undernourished ones in particular. Child undernutrition is the result of dietary deficiency. The deficiency, in turn, may arise from the caregivers' lack of financial capacity to purchase and provide adequate and balanced diets, or lack of knowledge about dietary diversity, appropriate child feeding, and caring practices. This shows that malnutrition is related to both medical and social conditions affecting the different dimensions of health: mental, physical, and social well-being. Therefore, successful management of SAM requires recognizing and correcting both the medical and social conditions (WHO, 1999). Health institutions in low-income contexts such as that of the present study usually deal with the medical conditions. Healthcare practice is usually guided by a medical model approach founded on the concept of diagnosis and a simple mechanical view of illness in terms of structural and/or functional failures of the body. Hence, only the patient (the SAM child) is targeted in the treatment process. Though the medical model copes well with the physical or organic components of the illness, it provides much less assurance for

[6] Caregiver refers to a mother, a father, grandparents, or any person in the family who continues living with the child after its discharge from hospital.

psychological factors such as external stresses and inner emotional conflicts developing during the course of, and as the eventual outcome of the severe malnutrition. Therefore, effective intervention needs to include psychosocial treatment by addressing both the psychological and the social effects of malnutrition. This requires working with not only the child, but also with the physical and the social environment of the SAM child. On the other hand, the social conditions in low-income contexts are more complex dynamics within the political, economic, and cultural factors, which compromise the effectiveness of the treatment of SAM. In spite of such complexities, there is some evidence showing the potential benefit of psychosocial intervention in the treatment of SAM children (Sally Grantham-McGregor et al., 1994; Sally Grantham-McGregor et al., 1983; B. Nahar et al., 2009; Baitun Nahar, Hossain, Hamadani, Ahmed, Grantham-McGregor, & Persson, 2012). However, the results of the studies are inconclusive across different developmental and nutritional outcomes. Moreover, the studies are criticized for having different types of biases (Daniel et al., 2017).

SAM children are weaker and make limited use of their large and small muscles. This reduces their mobility and affects their gross and fine motor functions, which in turn not only affects their physiological functions, but also limits their exploration, learning, and development by limiting their interaction with the physical and social environments. Therefore, the psychosocial treatment of SAM children should be combined with age-appropriate psychomotor activities that enhance the rehabilitation of motor functions and sensory integration, maintaining body balance and strengthening muscles, physiological functions, and eye-hand coordination.

In a psychomotor/psychosocial stimulation, both the child and his/her environment are targeted in order to strengthen the resilience of the SAM child to cope with the physical and psychological challenges associated with malnutrition. Such an intervention encompasses an emotional, social, and psychological support to boost the child’s confidence, independence, and adequate functioning. Therefore, a more comprehensive intervention model that addresses the multidimensional causes and effects of SAM is needed. The biopsychosocial model, which integrates the medical and the social models of disability, is recommended by the International Classification of Functioning, Disability and Health (ICF) as a framework which provides a coherent view of the different perspectives of health: biological, individual, and social (WHO, 2002). Accordingly, the psychomotor/psychosocial stimulation package has to be designed within the framework of the ICF model, which addresses the health conditions of SAM children within contextual factors: external environment and internal personal factors. To take such contextual factors into account, the psychomotor/ psychosocial intervention has to be undertaken within the context of each SAM child's home conditions, and include services and activities that enhance physiological functions and strengthen anatomical parts of the body, and contribute to cognitive, language, emotional, and social development through activities and participation in life situations in the form of play.

The effectiveness of psychomotor/psychosocial interventions for children, however, depends on how they align with the course of child development and the plasticity of the neural system. Aligning intervention activities with the growth and developmental changes during the different periods of a life span increases the effectiveness of the intervention. The earlier the intervention, the better the outcomes (Committee on Integrating the Science of Early Childhood Development, 2000; Guralnick, 1998). Such interventions should target children as well as their family, and comprise preventive and/ or curative activities, emotional and psychological support, educational and related services for infants and toddlers identified through diagnosis, or suspected through screening, or have high risks or probability for developmental delays. Early life has been considered as a critical period for intervention (National Scientific Council on the Developing Child, 2007). Since the nervous system develops in utero and during infancy and childhood, it is vulnerable to macronutrient deficiencies during these periods (Diop et al., 2006). Hence, the period in utero and up to two years of age, which is often termed as a "window of opportunity period", has often been considered a vulnerable time for malnutrition. Accordingly, most early psychosocial interventions on malnourished children targeted those under three years of age (J. Gardner, Walker, Powell, & Grantham-McGregor, 2003; J. M. M. Gardner et al., 2005; Sally Grantham-McGregor et al., 1994; Sally Grantham-McGregor et al., 1987; S. M. Grantham-McGregor et al., 1991; Sally M Grantham-McGregor et al., 1997; B. Nahar et al., 2009; Baitun Nahar, Hossain, Hamadani, Ahmed, Grantham-McGregor, & Persson, 2012; Susan P Walker, Chang, Powell, & Grantham-McGregor, 2005; Susan P Walker, Chang, Powell, Simonoff, & Grantham-McGregor, 2006). However, arguments are emerging and suggestions have been made to broaden the narrow "window of opportunity" period to five years of age (Committee on Integrating the Science of Early Childhood Development, 2000). An observational cohort study of more than 3000 children from four low- and middle-income countries (Ethiopia, India, Peru and Vietnam) seems to support this argument. An assessment of the impact of child nutrition, as measured by growth, at different periods from conception through middle childhood, on cognitive achievement in early adolescence showed a significant relationship between cognition and changes in growth into adolescence. Child growth occurring after the age of two is responsive to weather shocks and has a large effect on cognitive achievement in early adolescence (Georgiadis, 2017). This finding is contrary to the usual assumption that the relationship between child growth and cognition is less important beyond the first 2 years or 1000 days of life (in utero and 2 years after birth). Based on this finding, they concluded that positive changes in child growth later in a child's life have important implications for cognition (Crookston, Forste, McClellan, Georgiadis, & Heaton, 2014). In low-income countries, there is a high prevalence of at-risk children spanning the "window-of-opportunity" period. Like the younger children, these children also need risk-minimizing rehabilitations in order to attain their developmental potential. Unlike many earlier studies, which targeted SAM children six to 24 months of age, the present work has included older children above two years of age and examined the effect of psychomotor/psychosocial intervention on their developmental and nutritional outcomes.

1.6. The intervention in the present work

A large number of SAM children are treated at Jimma University Specialized Referral Teaching Hospital, located in Jimma Zone, 360 kilometres south west of the Ethiopian capital, Addis Ababa. The University hospital admits referrals from other hospitals and health centres in the Jimma Zone and neighbouring districts. SAM children treated at this hospital are heterogeneous in their ages, degrees and types of malnutrition. Some children are wasted, oedematous, stunted-wasted, and/ or stunted-oedematous. A single anthropometric index, therefore, may not accurately show the nutritional profiles of such heterogeneous groups. A recent study conducted in South-west Ethiopia has shown that the conventional indices underestimate the prevalence of undernutrition by 20.7%., and recommends the use of a composite index of anthropometric failures as a better approach (Fentahun, Belachew, & Lachat, 2016). Admission to the hospital is in line with WHO's recommendation and based on the protocol prepared by the Ethiopian Ministry of Health (Chamois et al., 2007). The SAM children are treated medically for complications and associated illnesses. Dietary treatment is also given in the Nutritional Rehabilitation Unit (NRU). The hospital does not keep the children until they are fully recovered. Discharges are made for follow-up as an out-patient. Caregivers are advised to take the SAM child to a nearby health centre for periodic evaluation. Ready-to-use-therapeutic-food (RUTF) is also collected from such centres. This PhD work also documents the effect of psychomotor/psychosocial intervention to supplement such services.

1.6.1. Theoretical underpinnings for the intervention

Child development is affected by the socio-cultural environment in which children live and grow up (Bronfenbrenner, 1970; Vygotsky, 1978). Through advances in neuroscience there is now a better understanding of how the human brain develops. Studies on animals and humans show that healthy brain development depends on early experiences. If the brain is exposed to different visual, auditory, and tactile information, it engages in active processing that contributes to brain wiring (Restak, 2001). Early sensory stimulation activates different parts of the brain to differentiate neuron functions and establish sensory pathways. Sensory pathways influence the development of neural pathways to other parts of the brain involved in coping, movement, language, cognition, and biological pathways, including the immune and hormone systems (Keating, Clyde, & (Eds), 1999). Environments enriched with meaningful, age-appropriate and enjoyable activities appealing to the different sense organs are supportive for brain development in young children (Committee on Integrating the Science of Early Childhood Development, 2000; Shonkoff, 2009, 2010). Family and home are the first immediate social and physical environments in which the brain of a young child starts to be shaped. Through play and mediation of their caregivers, children engage in meaningful interactions and learn about world around them, develop their cognitive, emotional, language, and social competences.

1.6.2. Child play and psychosocial development

Play is a spontaneous or organized activity which not only provides enjoyment and entertainment but also engages children in problem-solving and flexible thinking (Parham, 2008). Play helps children to undergo normal brain development, to conquer fear while exploring their environment and practice adult roles, and develop new competencies that lead to enhanced confidence and resiliency (Kenneth R. Ginsburg and the Committee on Communications & Health, 2007). Play is a language in which children express their needs, emotions, and how they feel about themselves and the world around them. It provides time and space for children to explore and gain skills that they will use in adult life. It also produces a sense of joy and mastery. When carried out in group, it enhances the development of the skills of collaboration and cooperation. Children express their feelings (happiness, fears, imaginations), strengthen their muscles, develop social relationships, communication skills, emotional and cognitive development through different types of games. Naturally, children like to play unless they have problems. Child play can be more effective through mediation. Responsive interactions make play more meaningful and engage children in physically, mentally, emotionally and socially important activities. In doing so, the mediational role of caregivers in facilitating play is very important for the holistic development of children. Interactions with children has to be guided by an understanding of children's needs and abilities. However, sometimes caregivers fail to serve as effective mediators due to a lack of education on play and workload (Lynch, Prellwitz, Schulze, & Moore, 2017). Therefore, in an intervention activity, these issues need to be addressed. Caregivers have to be sensitized about the importance of play in child development, and equipped with basic knowledge and skills on responsive interaction and play with children. Since all family members play a significant role through their daily contacts, it is also important to include them as key actors in intervention programs on children.

1.6.3. Role of caregivers

Family members are important providers of care and mediators of child play. Yet, some may not be aware of the importance of play or have the skills required to make play more meaningful in enhancing physical, cognitive, emotional, and social development. Child development starts with a dependency on caregivers. The developing individual relies on the vast pool of transmitted experiences of others. Hence, social interaction is considered as a core issue in human development (Miller, 2002; Vygotsky, 1978). It is through interactions that a child engages in physical activities that develop motor functions, in mental activities that develop cognitive functions and in social activities that enhance language, communication, and emotional development. The role of caregivers in mediating between the child and her/his environment for meaningful interactions and learning is critical (Reueven Feuerstein, 1980; Reuven Feuerstein, Klein, Tannenbaum, & (Eds), 1991; Klein, 1987, 1991). Recent scientific evidence strengthens the importance of caregivers' relationships with children and the role of reciprocal interaction in fuelling the developmental process of young children. Regardless of the hardships or threats children have experienced in life, responsive relationships with parents and caregivers can buffer children from developmental disruptions and help them build resilience (Center on the Developing Child at Harvard University, 2016).

In this work, the focus is on play as a medium of interactions for children, and caregivers as key mediators of the interactions. The psychomotor/ psychosocial intervention package brings these two actors together to enhance the development of the children within their own home and family context. However, child play and its benefits is not well-understood among some societies, who want to shape their children through adult standards. Play is considered as a childish behaviour and sign of immaturity, and children are given less freedom to play. Raising awareness about play and its significance is an important aspect of the present work.

1.6.4. The psychomotor/psychosocial stimulation

There are two pillars within this intervention package: the SAM child and the caregivers. The terms "psychomotor"/" psychosocial" are used to show that the intervention targets these two actors. The psychomotor component targets the SAM child and focuses on activities which strengthen the muscles, develop new competencies that lead to enhanced confidence and resiliency, and enhance the coordination of a body and mind that have been seriously affected by undernutrition. The psychosocial component underscores the importance of addressing the different dimensions of development such as cognitive, social, language, and emotional functions by involving significant others around the child. The combination "psychomotor/psychosocial" is used to indicate the multidimensionality of the intervention and its conceptual root within the framework of the International Classification of Functioning, Disability and Health (ICF). The ICF is a framework aimed at providing a unified and standard language for the description of health and health-related states from the perspective of the body, the individual, and society in two basic lists: (1) body functions and structures, and activities and participation (WHO, 2001). For the intervention to address the body functions and structures within the SAM child's personal and contextual factors, home-based family-centered play is crucial. It is a means of engaging the SAM child in motivational activities and meaningful participation with the involvement of primary caregivers and significant others by using community resources. To undertake this intervention in a hospital setting, a playroom and a playground furnished with play materials and equipment were arranged around the paediatric ward of the hospital. Since play is the language and primary activity of children, it was used as an enjoyable means of initiating the psychomotor/ psychosocial intervention at the hospital and continuing it at home after discharge.

1.6.4.1. Basic play materials

Play should be based on the intrinsic motivation of the child. It is therefore important to be guided by the lead of the child. This requires careful selection and provision of play materials that are liked by children, relevant to their age, and stimulate their senses. The SAM children were between six months and six years of age. Different play materials, which were appropriate for specific age groups, and those that could be used across different ages, were used (Fig. 1.2). Moreover, caregivers were encouraged to use locally available resources and cultural materials.

Figure 1.2: Age-category based play materials used for stimulation

1.6.4.2. Stimulation at playroom and playground

The play-based stimulation was given in a playroom alone or a playroom and a playground depending on the age and health condition of the SAM child. Younger and weaker children were not often taken to the playground. Play leaders demonstrate play activities to the SAM child and a caregiver (Fig.1.3-1.5).

Figure 1.3. Stimulation in playroom: a play leader with a SAM child and her father

Figure 1.4. Stimulation in play-room: a mother stimulating her SAM child under the supervision of a play leader

Figure 1.5. Stimulation at play-ground: a SAM child in the hands of a play leader, playing with other children

1.6.4.3. Stimulation at home and home follow-ups

According to the National Protocol on the management of SAM, SAM children are expected to be followed at a health centre in their vicinity. Before discharge from hospital, caregivers are usually advised to take the SAM child to a nearby health centre for periodic check-ups and for collection of ready-to-use-therapeutic-food (RUTF) for home-based supplementary feeding. However, it was learned during the home follow-ups that many SAM children were not getting adequate dietary supplementation services because there were no health centres nearby and there was a shortage of RUTF in some of the remote health centres. The children and families live in very poor conditions: inadequate diets, low or no dietary diversity, low sanitation, lack of pure drinking water, and a non-stimulating home environment. The SAM children were highly exposed to recurrent illnesses such as diarrhoea and pneumonia. In some cases, they defaulted and were re-admitted to hospital.

The main goal of the home follow-up in the present work was to continue the stimulations started at hospital. On discharge from hospital, the intervention SAM children were provided with some age-appropriate play materials. Additional play materials were supplied during the home visit, children were stimulated, and family members were shown how to use different materials and games to stimulate the child Moreover, information was provided to caregivers on childcare, health and nutrition. Three home visits were planned to be conducted in the 3rd, 7th and 13th week after discharge from hospital. Intervention nurses who provided the child stimulation and caregiver training at hospital visited each SAM child at his/her home within a six-month follow-up period. Stimulation was offered in a corner, or in any available space in or around the caregiver's home (Fig. 1.6). Children were shown some activities for imitation, and caregivers were encouraged to add cultural games and materials for the stimulation of the child.

Figure 1.6. Home-based stimulation of the SAM child and demonstration on how to play with new a play material offered

1.6.5. Measuring outcomes of the psychomotor/psychosocial stimulation

1.6.5.1. Growth outcomes

The nutritional status of a child is a measure of a child's growth status. Anthropometric measurements were made to determine the nutritional status.

The child's height/length, weight and mid-upper-arm-circumferences were measured using a length mat (for children < 2 years) or stadiometer (for children ≥ 2 years), digital weight scales and mid-upper-arm-circumference measuring tape respectively. The scores were transformed into Z-scores using WHO's Anthro or AnthroPlus (WHO, 2011) by taking the means of a standard reference population (WHO, 2006b).

1.6.5.2. Developmental outcomes

The children studied primarily in line with the main objective of the present study were patients with severe acute malnutrition and associated illnesses. These are children live in a low-income setting where specialized professionals are rare, and primary healthcare is provided by paraprofessionals. These SAM patients are weak, fragile, and have shorter concentration spans to undergo developmental diagnostic testing. Other than the prolonged and exhaustive diagnostic assessment, shorter and quicker assessments that do not require specially trained professionals are feasible to estimate the developmental profiles of such children. Hence, we opted to use two screening tools: one that combines both direct testing of the child with parental report and another one which collects information about the child from the caregiver through a structured interview. Two Western tools which were identified as suitable and adapted for use were the Denver Developmental Screening Test revised version (Denver II) (W. K. Frankenburg, J. Dodds, P. Archer, H. Shapiro, & B. Bresnick, 1992a) and the Ages and Stages Questionnaires Social-Emotional (ASQ:SE)(Squires, Bricker, & Twombly, 2003).

Figure 1.7. Home-based developmental assessment of a SAM child through direct testing and through parental report

The Ages and Stages Questionnaires: Social-Emotional is a parent-completed, child-monitoring system for social-emotional behaviours. This screening tool was adapted in order to assess the social-emotional competences of children from three to 65 months of age. There were 8 questionnaires for the age ranges 3-8, 9-14, 15-20, 21-26, 27-32, 33-41, 42-53, and 54-65 months. A total of 54 items (5, 6, 5, 5, 8, 8, 8, and 9 respectively for each age category in ascending order) were adapted and translated into the two major languages used in the study areas (Afan Oromo, the regional language, and Amharic, the federal language). The adaptation was made by a local psychologist and a European child psychiatrist, who worked together for a series of consultations with local psychologists and special education professionals working as lecturers in a higher education institution. Other academics familiar with the two local cultures and languages took part in discussions and translations. Details of the adaptation process of the ASQ:SE is not documented in this work.

The Denver II was adapted and standardized in the cultural context of the present study to assess the development in fine motor, gross motor, language and personal-social skills of children from birth to six years of age. Details of the process are discussed in Study I.

1.7. Overview of the studies

The aim of this work was to assess the effect of a family-centered play-based psychomotor/psychosocial stimulation on growth and developmental outcomes of SAM children from six months to six years of age. To achieve this aim, we conducted three studies (reported in Chapter 2) in two different phases. During the first phase, two child development screening tools that were found more suitable to use on the very weak and fragile SAM children were identified. The tools were adapted for use in a series of cross-sectional studies. We report the adaptation process of one of the tools. During the second phase, the adapted instruments were used and two studies were conducted. The first was a cross-sectional study aimed at examining the developmental performances of the SAM children in comparison with healthy children. The third was a longitudinal intervention study with a randomized controlled trial design aimed at examining the effect of the stimulation on nutritional and developmental outcomes of the SAM children. Below, the different studies are introduced in more detail.

Study 1. Adaptation and standardization of a Western tool for assessing child development in a non-Western low-income context

The primary outcome of interest in the present study was child development. However, there was a lack of culturally relevant tools to assess the development of children in the study setting. We therefore identified suitable tools and adapted them for use. Accordingly, the first study dealt with the adaptation and standardization of a child development assessment tool developed in the cultural context of a Western society, to make it culturally relevant for use in the study context. A cross-sectional study was conducted on non-malnourished healthy children. As part of the adaptation process, feasibility and reliability of the tool was assessed during different phases: exploratory survey on test items, pilot try-outs and further fine-tuning of test items adapted, pilot and major assessment of reliability, and standardization of test items. Study I reports the outcomes of these series studies. Of the 125 test items in Denver II, 36 items were adapted with most adaptations being in the personal- social domain. The ages of attaining milestones on the adapted tool was generally different from the ages in the original tool.

Study 2. Developmental performance of hospitalized severely acutely malnourished children under six in a low-income setting

To intervene, it is important to know the magnitude of the effect of SAM at its acute stage on different developmental domains. This allows identifying the developmental domains more seriously affected and thus in need of more attention during interventions. Therefore, with a cross-sectional approach we compared the developmental performances of severely acutely malnourished hospitalized children with age and sex-matched healthy children. The study showed that SAM affects all domains of development, with gross motor skills being most seriously affected.

Study 3. Effect of play-based family-centered psychomotor/psychosocial stimulation on the recovery of severely acutely malnourished children under six in a low income setting: a randomized controlled trial

The third study reports the effect of a play-based psychomotor/ psychosocial stimulation on growth and developmental outcomes of SAM children admitted to hospital for treatment (longitudinal approach). After randomly assigning the SAM children in parallel into control and intervention groups, the intervention group received psychomotor /psychosocial stimulation in hospital and at home. The study compared the changes in the nutritional and developmental outcomes of the two SAM groups during hospital and home follow-ups. The intervention children improved significantly on gross motor performance in hospital, and on fine motor performance during home follow-up. Moreover, the end-line performance of the SAM children followed for six months at home in both groups were compared with that of age-matched healthy children. No catch-up was attained for both the control and the intervention children except on social-emotional competences, which improved substantially for the intervention group though the difference from the control was not significant.

Chapter 3 summarizes and discusses the findings of the three papers and ends on concluding remarks, practical implications of the study findings, and suggestions for future research. The final section (Chapter 4) is a brief summary of the thesis in Dutch.

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Objectives of the studies

Studies conducted in this work (Fig. 1.8) are aimed mainly at evaluating the effect of psychomotor/psychosocial stimulation on the development, linear growth and nutritional status of severely acutely malnourished children 6 to 65 months of age (Study 3). In order to evaluate the intervention effect on development, the first step in the process was identifying, adapting and standardizing a child development assessment tool suitable for use in the socio-cultural context of the children (Study 1). An essential second step was to have a better understanding of the magnitude of the child development problems associated with severe acute malnutrition (Study 2). These three studies make up the dissertation: two original research articles published in peer-reviewed journals, and another one being under review.

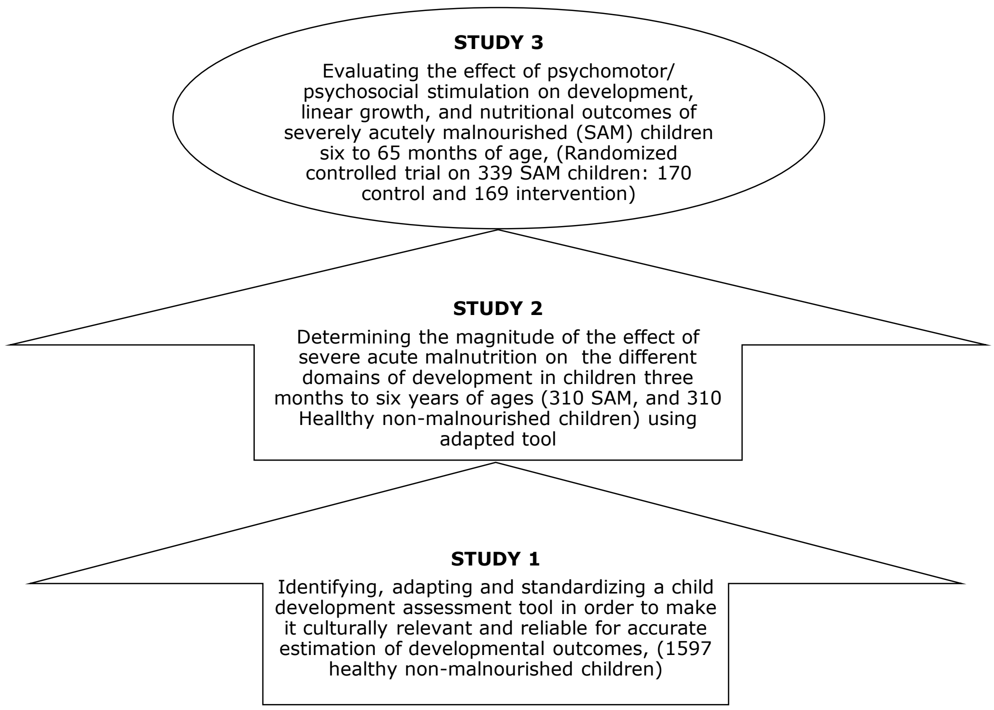

Figure 1.8. Flow of the objectives to the main goal of the dissertation

2

CHAPTER 2: STUDIES AND RESULTS

Study 1

STUDY 1: Adaptation and standardization of a Western tool for assessing child development in a non-Western low-income context

Adapted from: Teklu Gemechu Abessa, Berhanu Nigussie Worku, Mekitie Wondafrash Kibebew, Jan Valy, Johan Lemmens, Herbert Thijs, Wondwosen Kasahun Yimer, Patrick Kolsteren and Marita Granitzer

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2.1.1. Abstract

Due to a lack of culturally relevant assessment tools, little is known about children's developmental profiles in low income settings such as Ethiopia. The objective of this study was to adapt and standardize the Denver II to assess child development in Jimma Zone, South West Ethiopia. Culture-specific test items in Denver II were modified. After translation into two local languages, all test items were piloted and fine-tuned. Using 1597 healthy children 4 days to 70.6 months of age, the 25, 50, 75 and 90 % passing ages were determined for each test item as milestones. Milestone attainment on the adapted version and the Denver II were compared to the 90 % passing age. The reliability of the adapted tool was examined.

A total of 36 (28.8 %) test items, mostly from the personal-social domain were adapted. Milestone attainment ages on the two versions differed significantly on 42 (34 %) test items. The adapted tool has an excellent inter-rater on 123 (98 %) items, and substantial to excellent test-retest reliability on 119 (91 %) items. A Western developmental assessment tool can be adapted reliably for use in low-income settings. Age differences in attaining milestones indicate a correct estimation of child development requires a population-specific standard.

2.1.2. Introduction

Despite substantial child mortality reduction in Sub-Saharan Africa, many children under five are still developmentally at risk because of poverty and related risk factors such as malnutrition, poor health, and unstimulating home environments (Sally Grantham-McGregor et al., 2007). The magnitude of developmental problems is, however, unknown due to a lack of culturally relevant tools for assessing development. In the absence of such tools, it is also difficult to correctly determine the developmental effects of interventions which target children at risk. In rare studies conducted on children at developmental risk, researchers have used tools originally created for European and North American technological societies by either translating or adapting them with little validation (Boivin et al., 1995; Drotar et al., 1999; Holding et al., 2004; Nampijja et al., 2010; Servili et al., 2010). Sometimes, culture-specific test items were totally dropped (Aboud & Alemu, 1995; Bhargava, 2000; Drewett, Wolke, Asefa, Kaba, & Tessema, 2001; Neumann, McDonald, Sigman, Bwibo, & Marquardt, 1991; Stoltzfus et al., 2001) or no adaptation was made (Hokjindee, Chongsuvivatwong, Lim, & Pruphetkaew, 2010; Lohausa et al., 2011; Nanthamongkolchai, Ngaosusit, & Munsawaengsub, 2007). One such Western tools adapted and used worldwide is the American Denver Developmental Screening Test (Frankenburg & Dodds, 1967) or its revised version, the Denver II (Frankenburg, Dodds, et al., 1992a). The Denver II is a revised version of the Denver Developmental Screening Test, developed in 1967. It was standardized in 1989 on 2,096 American children and published in 1992. It is a screening tool used to identify children between birth and six years old who have problems in the following areas: personal-social (self-help skills and socialization with others), fine motor (eye-hand co-ordination, and manipulation of small objects), language (production of sounds, ability to recognize, understand, and use language), gross motor (large muscle movements such as sitting, walking, jumping). The Denver II has been used in other countries such as Georgia, Singapore and Sri Lanka by adapting and standardizing it (Chikvinidze, Geladze, Natriashvili, & Tsigroshvili, 2003a; Lim, Chan, & Yoong, 1994; D. N. Wijedasa, 2012).Though it is simple, quick and feasible to use at institution and home settings to identify children at developmental risks (Frankenburg, 2002), Denver II has not been adapted and validated for use in many low-income countries in Africa, such as Ethiopia. An indigenous tool similar in style, however, was created for children in Malawi (Gladstone M, 2010). By using Denver II as a prototype, new test items that were more culturally relevant for Malawian children were created from the Denver Developmental Screening Test, the Denver II and the Griffiths Mental Development Scales.

The main objective of this research, therefore, was to adapt and standardize the Denver II for children between birth and six years of age in the low-income context of Jimma Zone, Ethiopia, for a more realistic assessment of their development.

2.1.3. Methods

2.1.3.1. Study setting

The study was conducted in Jimma Zone, South West Ethiopia. Within this zone, the population was estimated to be 2.8 million. Jimma Town is the Zonal Capital, with about 149, 166 inhabitants (Central Statistical Agency-Ethiopia, 2013). The town is home to more than nine ethnic and linguistic communities, communicating mostly in a federal language, Amharic, and a regional language, Afan Oromo. With a mixture of both urban and rural life styles, Jimma Town represents the diverse socio-economic, multicultural and multi-lingual Ethiopian society.

2.1.3.2. Adaptation process of the Denver II

The Denver II (Frankenburg, Dodds, et al., 1992a) comprises 125 test items grouped into four domains of child development: 25 personal-social (PS), 29 fine motor (FM), 39 language (LA) and 32 gross motor (GM). These test items are administered using a bell, glass bottle, set of 10 blocks, rattle, pencil, tennis ball, yarn, raisins, cup, white doll, white paper, and a baby bottle. In the adaptation process, both qualitative and quantitative approaches were used complementarily. Details of the qualitative approach are attached as an appendix. Adaptations involved identifying culture-specific test items, test objects or materials, and then modifying or replacing them to make them culturally relevant.

In some cases, instructions for test item administration and criteria of passing were modified.

2.1.3.2.1. Classifying test items under 'cross-cultural' and 'culture-specific' categories

All test items were first categorized into culture-specific and cross-cultural items. The cross-cultural relevance of tasks in the test items was assessed using International Classifications of Functions (WHO, 2007). Culture- specific items related to movement (e.g. running, jumping, hopping) were identified using a taxonomy of movement skills (Burton, 1998). Other specific movement skills related to sport, complex movement skills, and functional movement skills such as activities of daily living, work, and games are culture-specific. Cross-culturalism of items other than movements were assessed using *cross cultural psychology* (Berry, Poortinga, Segall, & Dasen, 2002): a branch of psychology which examines how cultural factors influence human behaviour, which aspects of human thoughts and behaviour are universal, and how cultural differences make people think, feel and act differently. Within this process a local team (psychologists, a special educator and paediatricians) and a Belgian team (child psychiatrist, a paediatrician/ nutritionist, a neuroscientist, a physiotherapist and an occupational therapists) worked together.

After translation into the dominant languages (Amharic and Afan Oromo), dialect appropriateness was checked. Two academics (each being a native speaker of one of the two languages) who are familiar with the study context independently made the translation into one of the languages. The independent translations were compared and fine-tuned by two other academics familiar with both languages and study context. The translations were piloted and further fine-tuned to ensure dialect appropriateness.

2.1.3.2.2. Pilot studies and draft versions

The test items were then piloted on apparently healthy children of accessible parents who consented orally to participate in the study. Draft I emerged based on a survey conducted in 2009 on 19 households. Four urban and

15 rural families were interviewed about the items which were identified as culture-specific (see Fig. 2.1.1).

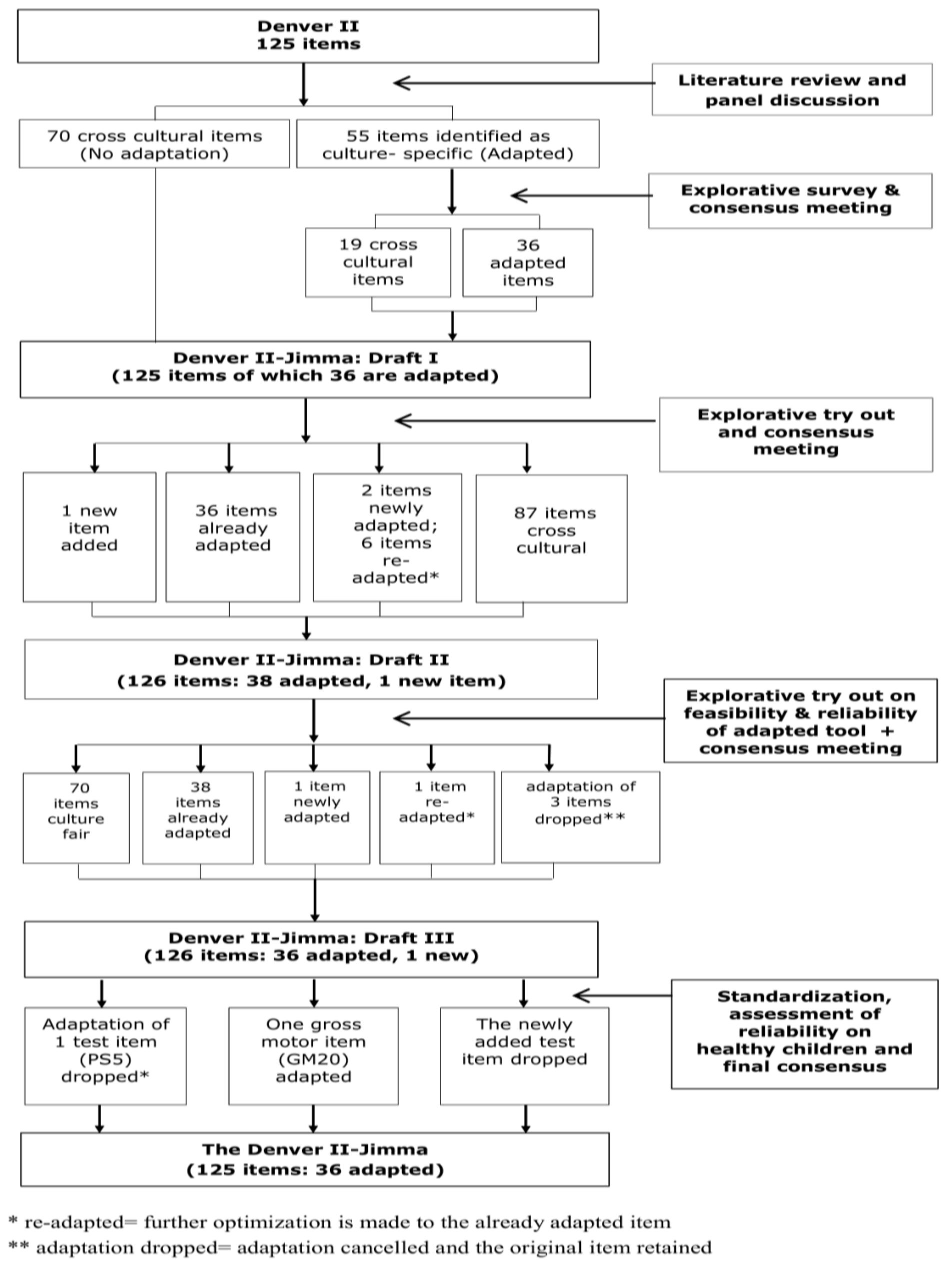

Figure 2.1.1. Adaptation and standardization process of the Denver II to Denver II-Jimma

Draft I was tried out on eight urban kindergarten children (26-60 months of age; mean=42.9; SD=±14.1). Three local study team members, trained in Denver II test item administration, did the testing and the problematic items were discussed at the multidisciplinary team meeting. Re-adaptations resulted in Draft II, which was further explored in 2010 for feasibility and reliability on 24 urban kindergarten children (mean age=51.4 months, SD ± 8.2 months). Testing was conducted by seven trained kindergarten teachers. Training was conducted first by demonstrating a video on how each of the test items in Denver II were administered and the changes that were made through the adaptation. Then, the trainees practiced administering each test item, first on each other, then on kindergarten children. The trainees took a proficiency test, and those who performed better in the test participated in data collection. Further adaptation resulted in Draft III. Figure 2.1.2 summarizes the adaptation process.

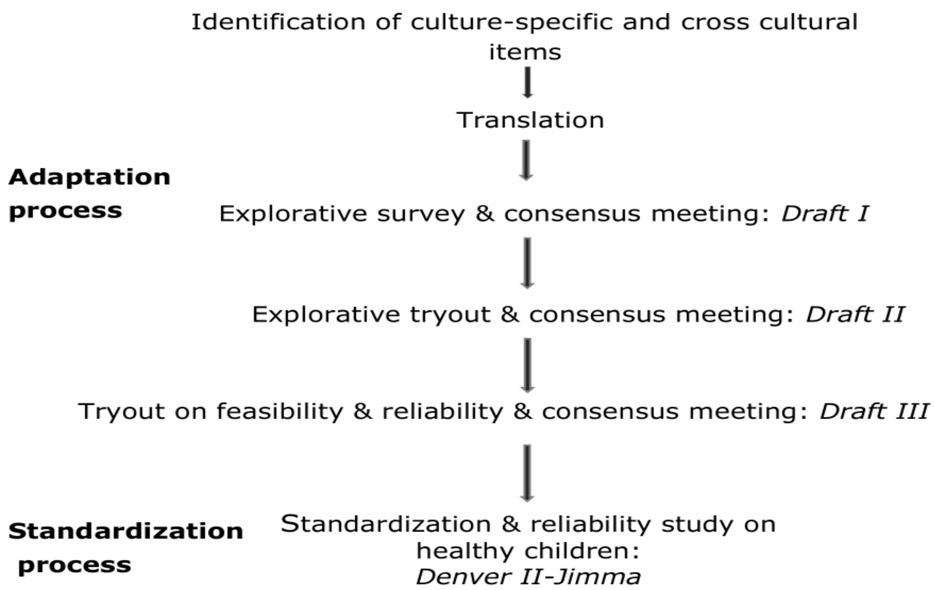

Figure 2.1.2. Flow of activities in the adaptation and standardization of the Denver II to Denver II- Jimma.

2.1.3.2.2. Large sample study and standardization

2.1.3.2.2.1. Sampling, inclusion and exclusion criteria

Trained nurses collected data using the third draft. Children under six in Jimma Town whose parents could afford to pay preschool education fees were targeted. Such children were assumed to belong to a middle or higher socioeconomic level and thus in a context for optimal development. Quota sampling was used to include children in the following age categories (in months): 0-2, 3-8, 9-14, 15-20, 21-26, 27-32, 33-41, 42-53, and 54-65.

Before testing a target child, the mother was interviewed using a 10-point checklist which listed the exclusion criteria. Children whose mother reported the presence of any of the following potential developmental risks were excluded: prematurely born, birth weight less than 2500g, very tiny body at birth, instrumentally delivered or delivered after 24 hours of labour, born twins or triplets, born with a chronic health problem, sick during the first year after birth, having observable impairments affecting sight or/and hearing, or/and mobility, having a mother who was seriously sick during pregnancy. Additionally, anthropometric measurements were made to assess the nutritional status and exclude malnourished children. Weight was measured with a calibrated digital weighing scale; mid-upper-arm-circumference (MUAC) with a MUAC tape. Anthropometric indices related to length/height were not used for fear of measurement inaccuracy, as some children were nervous while positioning them for measurement. Earlier studies have also used weight-for-age to determine a child's nutritional status (Aboud & Alemu, 1995; Onis, Monteiro, Akré, & Clugston, 1993) because the weight-for-age is considered more comprehensive than the height-for-age (WHO Working Group, 1986). Assessment was done (if the child was well) in the following sequence: developmental assessment, measuring weight, MUAC.

The questionnaire and study consent form were dispatched to parents of children attending a private kindergarten in Jimma town. The homes of parents who signed the consent form were visited. From 3502 children, only 1682 (mean age=31.2, SD=17.75 in months) who were eligible according to the inclusion criteria were tested. The age of the children ranges from 4 days to 73.3 months.

Initially, 1552 children were tested at home from 11 January to 21 June 2011 and later, 130 children of lower ages (< 10 months) were added. Two children of unknown nutritional status and eighty-three malnourished children were excluded during the analysis, based on weight for age Z-score (WAZ) ≤-2, or mid-upper-arm-circumference Z-score (MUACZ) ≤-2 when WAZ was absent.

The study complied with the Helsinki Declaration (World Medical Association, 2001) and was reviewed and approved by The Ethical Clearance Board of Jimma University, Ethiopia, and Comité voor Medische Ethiek Universiteit Hasselt, Belgium. Written and oral consents of parents were obtained and children were always tested in the presence of caregivers.

2.1.3.2.2.2. Assessment of feasibility and reliability

The feasibility of each test item (meaningfulness of test items, their practicality and ease of administration) was documented during data collection and discussed at a final consensus meeting. Inter-rater and test-retest reliabilities were assessed for each test item. Ten female clinical nurses worked in pairs alternately as a tester or an observer. Independent scores were generated for each child by a tester and an observer. These scores by testers and observers were calculated as percentages of agreement to determine the reliability of the test items. Inter-rater reliability was tested on 409 children. Within an average interval of 14 days, 147 of these were tested for test-retest reliability. Inter-rater reliability was not calculated during a re-test condition.

2.1.3.2.2.3. Test item administration and scoring system

Test item administration and scoring is the same as in Denver II manual (Frankenburg, Dobbs, Archer, Shapiro, & Bresnick, 1992). Each test item on Denver II is presented on a chart by a horizontal bar partitioned into 25, 50, 75 and 90 percentile ages of passing the items. To test a child, his or her age is calculated and a vertical age-line is drawn on the test chart. The testing starts from a test item completely to the left of the age-line. All test items passed by 75% or more children of the same age in the norming sample and by lower ages are counted for a child as *expected passes*. If a child passes three consecutive test items arranged on Denver II test chart, all items to the left are assumed to be passed because they are items achieved at a lower age. These items are called *implied passes*. If a child fails three consecutive test items, it is assumed that all other items arranged to the right on the Denver II chart are failed. These items are *implied failures*. Items passed by a child through testing are *tested passes*. Implied passes and tested passes are added up as *actual passes.* A child's raw score on each test item is marked as tested pass, implied pass, tested failure, implied failure, refusal, or no opportunity. Categorical and numerical scores were derived for statistical analysis.

Categorical score: For each test item, a binary outcome variable (pass/fail) was created: *pass* (tested pass items) and *fail* (tested failure and refusal). "No opportunity" to perform the item, "implied passes" and "implied failures" were treated as missing values.

Numerical score: The ratio of *actual passes* to the *expected pass*es was calculated as a *performance ratio* score.

2.1.3.2.2.4. Standardization

The objective of the standardization was to determine the ages at which 25%, 50%, 75% and 90% of the children pass each of the adapted test items using binary logistic regression.

2.1.3.3. Data management and statistical analysis

Data within the adaptation process (except for reliability) were analysed qualitatively. Whether or not a test item was culture-specific or cross-cultural was analysed using theoretical information and discussion among the research team. Data collected during drafting and re-drafting were discussed at interdisciplinary team meetings comprising local and Western professionals. Standardization data were entered into EpiData 3.1, double-checked, cleaned and exported to SAS 9.3 and STATA 12.1 for analysis. The WAZ and MUACZ scores were calculated as anthropometric indices using WHO Anthro and AnthroPlus and children's nutritional status determined against the WHO reference standard (WHO, 2011).

Predicted ages at which 25%, 50%, 75% and 90% of the norming sample passed each test item were derived from the models and calculated as milestone ages. Using the categorical score "pass/fail", a binary logistic regression model was fitted for each test item by entering child age in days as a single covariate using the following logistic regression equation:

$$P = \frac{e^{(\beta_0+\beta_1 X)}}{1+e^{(\beta_0+\beta_1 X)}},$$

where P is the probability that a child passes a given test item;

β_0 *is the intercept*; X *is age of child in days*; β_1 *is the coefficient of* X .

Predicted probabilities of passing were calculated from alpha (β_0) and beta (β_1) coefficients. Appropriatenes of the fit was assessed using Hosmer and Lemeshow test statistic at 5% level of significance. Items with poor model fit (p-value <0.05) were refitted using cubic splines (Harrell, 2012).

Age of attaining milestones by Denver II and Denver II-Jimma norming samples were compared on 90 percentile age. More than 10% difference was considered clinically significant.

Reliability was assessed at item and domain levels. Item reliability was calculated as a percentage of agreement between a tester score and an observer score (inter-rater), and between the first test and retest scores (test-retest) for the same child. Chance agreements were corrected using Cohen's kappa. Kappa values by Landis and Koch (Landis & Koch, 1997) were used for interpretation: value below 0.20 as slight; between 0.21 and 0.40 as fair; between 0.41 and 0.60 as moderate, between 0.61 and 0.80 as substantial, and between 0.81-1.00 as excellent agreement. Where kappa could not be calculated, percentages of agreement for events were determined: 70 % or higher was considered acceptable.

Domain reliability was evaluated using intra-class correlation coefficients. First, performance ratio scores were generated for each of the four domains separately. Then, the correlations between tester and observer performance ratio scores at two testing moments (test and retest) were computed for each domain as inter-rater and test-retest intra-class correlation.

2.1.4. Results

2.1.4.1. Outcome of the adaptation

Of the 125 Denver II test items, 55 (20 PS, 18 FM, 15 LA, 2 GM) were theoretically identified as culture-specific. These 55 items were piloted through an exploratory survey and discussed at a consensus meeting. Only 36 of these needed adaptation. The other 19 items were retained as per the original (Fig**.**2.1.1). A try-out revealed difficulties with eight (6 LA and 2 PS) test items. Further fine-tuning resulted in Draft II (36 adapted, 1 newly added, 89 original Denver II items). Inter-rater reliability of Draft II was excellent (kappa > 0.83) for all tested items. For items with skewed data distribution, kappa could not be computed. Their percentages of agreement, however, were all acceptable (71.4 to 95.2).

Some test items were found to be practically difficult to administer or still difficult for children to understand even after initial adaptation. Hence, to make sure that test items were feasible to administer, understandable for children and caregivers, further adaptations were made. One item from PS was adapted, another was re-adapted, and the adaptations of three LA items were dropped. This resulted in the Denver II-Jimma-Draft III, which comprises 36 adapted (18 personal socials, 10 fine motor, 8 language), 1 newly added (toilet going), and 89 original Denver II items.

At the final consensus meeting following the standardization study, one gross motor (walk up-steps) was adapted, the newly added item was dropped, and the adaptation of one personal-social item was dropped. This resulted in the final Denver II-Jimma having 36 adapted items (Table 1).

2.1.4.2. Outcome of the standardization

2.1.4.2.1. Characteristics of the standardization sample

A nearly equal number of boys and girls participated in the study. About 95% of the caregivers rated themselves as belonging to a middle or higher socio-economic standard.

Table 1 Descriptions of adaptation made to the Denver II test items to make Denver II- Jimma

Denver II test items adapted	Item code	Description of adaptation of the item
Work for toy[a]	*PS5*	*Rattle or culturally used tools such as small pebbles " calle" or " elela" were selected.*
Feed self	PS6	The items "cracker", "cookie" or "any finger food" were replaced by locally used food such a piece of "bread", "cake", "biscuit", "injera" or a piece of sugar-cane.
Play pat-a-cake	PS7	Replaced by "play a clapping game": a culturally equivalent game played by clapping hands.
Wave bye-bye	PS9	Modified Cultural difference in expressing goodbye: "saying" or "waving" goodbye.
Imitate (household) activities	PS11	Activities such as "vacuuming", or "talking on the phone" were replaced by activities such as ...."cooking" or "washing clothes".
Drink from cup	PS12	….child can hold a regular cup or glass and drink from it without help replaced by a regular "cup or glass" or any suitable container used in the family.
Use spoon/fork	PS14	Modified as "eat using hand or spoon/fork. The child uses a spoon or fork to eat. is modified as "the child is able to eat independently by using his/her fingers or a spoon or fork".
Remove garment	PS15	…items such as…."jackets", "pants", are modified as…items such as "blouse", "dress" or "trousers".
Feed doll	PS16	The criterion to pass the test item "if the child places the bottle to the doll's mouth, or tries to put it to the mouth"…is modified as "if the child imitates putting food into the doll's mouth or if the child imitates breast feeding". The use of bottle feeding is being discouraged and many mothers do not practice. Since toy bottle was found strange for many children, performing the task is not expected to pass the test item.
Put on clothing	PS17	….clothing, such as "underpants", "socks" are modified as …clothing, such as "blouse", "trousers", "dress", "skirt"
Brush teeth with help	PS18	Replaced by "wash mouth with help"…if the child "brushes his/her teeth with some help"…is modified as if the child "washes his/her mouth with some help".
Wash and dry hands	PS19	Criteria for passing the test item is modified as…child can "wash both sides of hands properly" (because hands are culturally dried by dripping water off the hands). Use of soap and towels are not required to pass the item.
Name friend	PS20	Replaced by "name playmate".
Put on T-shirt	PS21	"pullover"…is replaced by "T-shirt" or "blouse" …
Dress, no help	PS22	First: "at least play-clothes"…is modified as …"his/her own clothes", because children may not have many alternative clothing. Finally: adaptation dropped.
Play board/card games	PS23	Modified as "play social games"…. "board" or "card" games, …"Candy Land" or "Old Maid"… is modified as "joins in simple "group games", like "hide and seek".
Brush teeth, no help	PS24	"brush teeth, no help" replaced by "clean face, no help"….if the child "washes his/her own teeth" …is replaced by…if the child "washes and dries" his/her

		face (eyes, nose, mouth and teeth) …. this is usually done by using water and fingers).
Prepare Cereal	PS25	First:…if the child can prepare a bowl of cereal ……is modified as …if the child can prepare his/her own breakfast, including taking bread (or injera,…) from the shelf, taking a cup and pouring a liquid (water, milk, juice) in it. Finally: modified as "serve oneself 'injera'" (cultural food served with stew).
Toilet going [b]	PS26	First: Toilet going (new item): Ask the caregiver if the child can independently use latrine or other facilities available for the family. PASS if they report the child can independently use toilet or latrine or available facility. Finally: item dropped.
Regard raisin	FM6	Is replaced by "Regard coffee bean".
Rake raisin	FM9	Is replaced by "Rake coffee bean".
Thumb-finger grasp	FM12	…"raisin" which is used as an object for child to grasp is replaced by "coffee bean".
Scribbles	FM15	The instruction…"do not show him/her how to scribble"… is modified as.…you may write your name using the pencil to let the child who have never ever seen a pencil before that it is something to write with.
Dump raisin, demonstrated	FM16	Replaced by "dump coffee bean, demonstrated".
Copy 0	FM23	The instruction" you may show how to hold the pencil" is added to familiarize a child who has never seen a pencil before.
Draw person – 3 parts, 6 parts	FM24 & FM 28	The instruction…"You may show how to hold the pencil"… is added to familiarize a child who has never seen a pencil before.
Copy +	FM25	The instruction…"You may show how to hold the pencil"… is added to familiarize a child who has never seen a pencil before.
Copy □	FM29	The instruction…"You may show how to hold the pencil"… is added to familiarize a child who has never seen a pencil before.
Body parts – 6	LA21	A testing object "white doll" replaced by a black or chocolate colour doll. The use of either a white doll or a chocolate colour doll based on need of child was suggested based on repeated observation.
Name colours – 1,4	LA27 & LA34	First: Criterion for passing test item modified as, "Child could pass the test if he/she refers to an object with the same colour: sky/water for blue, grass/tree for green, sun for yellow and blood for red. Finally: The "blue" and "green" colour cubes are replaced by "black" and "white" colour cubes.
Use of objects – 2, 3	LA28 & LA 30	.... "What is a 'pencil' used for?" …. is replaced by …."What is a 'bed' used for?"….
Define words – 5, 7	LA35 & LA39	The words "desk", "curtain", "lake", are replaced by the words "knife", "firewood", "river".
Opposites – 2	LA37	"If 'fire' is 'hot', 'ice' is..." was replaced by "if a stone is heavy, a feather/leaf is ….."
Walk up step [c]	GM20	Walk up steps where there are steps in homes, and/or walk up-ward on steep location/ climbs and passes over an elevated door-step.

[a] The adaptation of this test item was dropped at a final consensus meeting.
[b] Newly added test item removed at final consensus meeting.
[c] The adaptation of this test item was added at a final consensus meeting.

The Oromo, as the largest ethnic group, seem to have been fairly represented (45.1%). Only 9.3% of mothers of children enrolled in the study are illiterate (Table 2).

Table 2 Characteristics of study participants

Characteristics	No. (%)	Characteristics	No. (%)
Children's (n=1682)		Mother's (n=1588)	
Sex		*Ethnicity*	
Male	833 (49.5)	*Oromo*	716 (45.1)
Female	849 (50.5)	*Amhara*	363 (22.9)
Nutritional status		*Tigre*	46 (2.9)
Normal range [a]		*Gurage*	140 (8.8)
Male	789 (46.9)	*Dawuro*	148 (9.3)
Female	808 (48)	*Keficho*	72 (4.5)
Malnourished [b]		*Wolaita*	30 (1.9)
Male	43 (2.6)	*Others*	62 (3.9)
Female	40 (2.4)	*Missing/Unknown*	11 (0.7)
Unknown status		*Perceived socio-economic status*	
Male	1 (0.06)		
Female	1 (0.06)	*High*	58 (3.7)
		Middle	1443 (90.9)
Mother's (n=1588)		*Low*	65 (4.1)
		Very low	0
Education level		*Missing/unknown*	22 (1.4)
Illiterate	147 (9.3)	Religion	
Grades 1-8	546 (34.4)	*Islam*	558 (35.1)
Grades 9-12	485 (30.5)	*Christian (Orthodox)*	725 (45.7)
12+ certificate	98 (6.2)	*Christian (Protestant)*	271 (17.1)
Diploma	247 (15.6)	*Christian (Catholic)*	23 (1.4)
Degree and above	55 (3.5)	*Others*	6 (0.4)
Missing/unknown	10 (0.6)	*Missing*	5 (0.3)

[a] (WAZ >-2 where both WAZ and MUACZ score are present; and MUACZ >-2 where WAZ score is missing); [b] (WAZ ≤-2 where both WAZ and MUACZ score are present; and MUACZ ≤-2 where WAZ score is missing) WAZ=Weight-for-age-Z-score; MUACZ=Mid-upper-arm-circumference Z score.

2.1.4.2.2. The Denver II-Jimma Age Milestones

Of the 126 test items separately fitted on logistic model, 66 items fitted well. Three items (PS1, LA1, GM1) could not be fitted because all tested children passed them. Fifty-seven items showed poor fit (13 PS, 18 FM, 11 LA, 15 GM). The model fitness for 39 of these were improved by refitting using cubic splines. On many items, the Denver II-Jimma differed from Denver II on 50%, 75% and 90% ages of attaining milestones (Table 3).

Table 3 The Denver II-Jimma with its age norms (in months) for 25%, 50%, 75% and 90% of children passing the test items within the different domains

Item code	Item label	25%	50%	75%	90%	Item code	Item label	25%	50%	75%	90%
	Personal social domain						Fine motor domain				
PS1	Regard face	birth [b]	birth [b, d]	birth [b, d]	birth [b, d]	FM1	Follow to midline	birth [b]	0.1[f]	0.1[e]	0.2[e]
PS2	Smile responsively	0.8	1.1[f]	1.3[d]	1.6[d]	FM2	Follow past midline	1.3	1.5[e]	2.2[e]	2.7[d]
PS3	Smile spontaneously	1.1	1.4[e]	1.6[f]	1.9[e]	FM3	Grasp rattle	2.4	3.0[d]	3.6[d]	4.1[d]
PS4	Regard own hand	1.6	1.,8[e]	3.2[e]	4.1[d]	FM4	Hands together	2.5	3.1[f]	3.7[f]	4.3[d]
PS5	Work for toy	3.1	4.5[d]	6.0[f]	7.6[f]	FM5	Follow 180 degrees	3.1	3.7[f]	4.3[f]	4.9[d]
PS6	**Feed self [a]**	4.0	5.9[d]	8.2[f]	10.5[f]	FM6	**Regard coffee bean [a]**	4.1	4.5[f]	5.0[f]	5.4[d]
PS7	**Play clapping game [a]**	6.9	8.1[e]	9.4[d]	10.6[d]	FM7	Reaches	4.2	4.7[d]	5.2[d]	5.6[d]
PS8	Indicate wants	6.1	8.1[e]	10.1[d]	12.2[d]	FM8	Look for yarn	4.9	5.4[d]	6.0[d]	6.6[d]
PS9	**Wave bye-bye/Say good-bye [a]**	8.2	10.0[f]	11.8[f]	13.6[d]	FM9	**Rake coffee bean [a]**	5.3	5.9[d]	6.4[d]	6.9[d]
PS10	Play ball with examiner	10.4	12.,2[f]	14.0[f]	15.8[d]	FM10	Pass cube	6.2	7.4[f]	8.5[f]	9.7[f]
PS11	**Imitate activities [a]**	9.7	11.6[d]	13.4[d]	15.2[d]	FM11	Take 2 cubes	5.8	6.9[f]	8.2[f]	9.5[d]
PS12	**Drink from cup or glass [a]**	9.7	11.8[d]	13.9[d]	16.0[d]	FM12	**Thumb-finger grasp [a]**	6.5	7.5[d]	8.7[d]	9.9
PS13	Help in house	12.9	15.9[f]	18.4[f]	20.9[f]	FM13	Bang 2 cubes held in hands	7.4	9.3[f]	11.3[f]	13.3[f]
PS14	**Eats using spoon/fork/fingers [a]**	11.7	14.5[d]	17.2[d]	20.0	FM14	Put block in cup	8.7	10.2[d]	11.7[d]	13.1[d]
PS15	**Remove garment [a]**	15.5	20.4[f]	24.5[f]	28.6[f]	FM15	**Scribbles [a]**	10.7	13.4[d]	16.0[d]	18.6[f]
PS16	**Feed doll [a]**	14.4	19.5[f]	24.5[f]	29.7[f]	FM16	**Dump coffee bean, demonstrated [a]**	10.9	13.5[d]	16.0[d]	18.5[d]
PS17	**Put on clothing [a]**	25.3	31.8[f]	38.1[f]	44.5[f]	FM17	Tower of 2 cubes	12.6	15.6[d]	18.3[d]	21.0[d]
PS18	**Wash mouth with help [a]**	20.4	24.8[f]	29.1[d]	33.4[d]	FM18	Tower of 4 cubes	16.4	19.3[d]	22.2[d]	25.1[d]
PS19	**Wash and dry hands [a]**	22.9	27.4[f]	32.4[f]	37.4[d]	FM19	Tower of 6 cubes	19.7	23.1[d]	26.6[d]	30.1[d]
PS20	**Name playmate [a]**	22.8	28,3[d]	33.4[d]	38.6[d]	FM20	Imitate vertical line	25.9	32.4[f]	37.7[f]	43.0[f]
PS21	**Put on t-shirt [a]**	34.2	40.8[f]	47.3[f]	53.8[f]	FM21	Tower of 8 cubes	22.1	29.4[f]	35.0[d]	40.6[d]
PS22	**Dress, no help [a]**	43.9	50.5[f]	57.0f	63.5[f]	FM22	Thumb wiggle	27.0	32.8[d]	38.4[d]	44.2[d]
PS23	**Play social games [a]**	31.8	41.6[f]	51.2[d]	60.9[d]	FM23	**Copy [a] O**	38.7	43.1[d]	47.3[d]	51.6[d]
PS24	**Clean face, no help [a]**	37.9	46.8[f]	55.5[d]	64.4[d]	FM24	**Draw person—3 parts [a]**	44.0	48.2[d]	52.3[d]	56.4[d]
PS25	**Serve oneself *injera* [a]**	31.7	46.5[d]	61.2[f]	76.0[d]	FM25	Copy [a] +	33.8	40.4[d]	46.9[d]	53.4[d]
PS26	Toilet-going [c]	60.1	70.4[d]	80.6[d]	90.8[d]	FM26	Pick longer line	33.8	40.4[d]	46.9[d]	53.4[e]
						FM27	Copy □ demonstrated	45.7	51.8[d]	57.7[d]	63.6[d]
						FM28	**Draw person—6 parts [a]**	52.4	57.5[d]	62.4[d]	67.4[d]
						FM29	**Copy [a]** □	52.3	58.2[d]	64.0[d]	69.8[d]
	Language domain						Gross motor domain				
LA1	Respond to bell	birth [b]	birth [b, d]	birth [b, d]	birth [b, d]	GM1	Equal movement	birth [b]	birth [b, d]	birth [b, d]	birth [b, d]
LA2	Vocalizes	birth [b]	birth [b, d]	0.3[f]	1.0[f]	GM2	Lift head	birth [b]	0.1[f]	0.4[f]	0.7[f]
LA3	"Ooo"/ Aah	1.4	1.5[f]	1.6[d]	1.6[e]	GM3	Head up 45°	1.6	2.4[f]	2.3[f]	2.6[d]
LA4	Laugh	2.0	2.2[f]	2.5[d]	2.7[e]	GM4	Head up 90°	2.9	3.2[f]	3.6[f]	3.9[d]
LA5	Squeals	2.2	2.5[f]	2.8[d]	3.2[e]	GM5	Sit head steady	3.0	3.3[f]	3.6[f]	3.9[d]
LA6	Turn to rattling sound	3.7	4.3[f]	4.8[d]	5.4[d]	GM6	Bear weight on legs	3.1	3.4[f]	3.6[d]	3.8[e]

LA7	Turn to voice	4.5	5.2[f]	5.8[d]	6.5[d]	GM7	Chest up-arm support	3.9	4.3[f]	4.6[f]	4.9[d]
LA8	Single syllables	4.6	5.5[d]	6.3[d]	7.1[d]	GM8	Roll over	3.8	4.4[f]	4.9[f]	5.4[d]
LA9	Imitate speech sounds	5.2	6.5[f]	7.8[f]	9.1[d]	GM9	Pull to sit, no head lag	4,4	4.9[f]	5.5[f]	6.0[d]
LA10	Dada/Baba/Mama, non-specific	5.7	6.7[d]	7.8[d]	8.8[d]	GM10	Sit, no support	5,4	6.0[d]	6.6[d]	7.3[d]
LA11	Combine syllables	6.2	7.5[f]	8.8[f]	10.1[d]	GM11	Stand, holding on	6,5	7.3[d]	8.3[d]	9.3[d]
LA12	Jabbers	7.0	8.5[f]	10.0[f]	11.5[d]	GM12	Pull to stand	7,2	8.0[d]	8.9[d]	9.9[d]
LA13	Dada/Mama/baba, specific	8.8	10.2[f]	11.6[d]	12.9[d]	GM13	Get to sitting	7,4	8.3[d]	9.2[d]	10.1[d]
LA14	One word	10.1	11.9[d]	13.6[d]	15.3[d]	GM14	Stand 2 seconds	8,6	9.7[d]	10.7[d]	11.6[d]
LA15	2 words	11.5	13.8[f]	15.9[d]	18.0[d]	GM15	Stand alone	9,8	11.3[d]	12.3[d]	13.4[d]
LA16	3 words	13,5	15.6[f]	17.7[f]	19.8[d]	GM16	Stoop and recover	11,6	13.2[d]	14.8[f]	16.4[f]
LA17	6 words	16,5	19.1[f]	21.8[f]	24.4[f]	GM17	Walk well	11,3	13.1[d]	14.9[f]	16.7[f]
LA18	Point 2 pictures	20,8	24.0[f]	27.2[f]	30.3[f]	GM18	Walk backwards	11,9	14.9[d]	17.4[f]	19.9[f]
LA19	Combine words	18,7	21.3[d]	23.9[d]	26.4[d]	GM19	Runs	14,4	16.6[d]	18.9[d]	21.2[d]
LA20	Name 1 picture	20,1	23.2[f]	26.2[f]	29.3[d]	GM20	**Walk up steps [a]**	13,9	16.9[d]	19.6[d]	22.3[d]
LA21	**Body parts 6 [a]**	20,3	23.0[f]	25.6[f]	28.2[d]	GM21	Kick ball forward	14,2	17.6[d]	21.0[d]	24.4[d]
LA22	Point 4 pictures	25,9	31.0[f]	35.9[f]	40.9[f]	GM22	Jump up	24.0	27.0[f]	31.0[f]	35.0[f]
LA23	Speech, half understandable	20,5	24.2[f]	27.8[d]	31.5[e]	GM23	Throw ball overhand	16.9	22.1[d]	27.2[f]	32.4[d]
LA24	Name 4 pictures	27,6	32.5[f]	37.3[f]	42.1[f]	GM24	Broad jump	31.7	35.6[d]	39.3[f]	43.1[f]
LA25	Know 2 actions	24,5	29.5[d]	34.4[d]	39.4[d]	GM25	Balance each foot 1 second	23.4	28.9[d]	33.0[d]	37.1[d]
LA26	Know 2 adjectives	30,9	35.1[d]	39.1[d]	43.3[d]	GM26	Balance each foot 2 seconds	23.9	31.2[e]	36.4[e]	41.6[e]
LA27	**Name 1 colour [a]**	40,3	45.1[d]	49.8[f]	54.6[f]	GM27	Hops	31.9	38.5[d]	45.0[d]	51.5[d]
LA28	**Use of 2 objects [a]**	30,4	35.6[f]	40.7[d]	45.8[d]	GM28	Balance each foot 3 seconds	29.8	36.1[d]	42.2[e]	48.4[e]
LA29	Count 1 block	36,6	41.9[d]	47.0[f]	52.2[f]	GM29	Balance each foot 4 seconds	33.8	40.0[e]	46.0[e]	52.1[e]
LA30	**Use of 3 objects [a]**	32,3	37.5[d]	42.7[d]	47.8 [d]	GM30	Balance each foot 5 seconds	39.2	44.8[e]	50.2[e]	55.8[e]
LA31	Know 4 actions	32,4	38.5[e]	44.4[f]	50.4[d]	GM31	Heel-to-toe walk	49.1	55.5[d]	61.8[d]	68.1[d]
LA32	Speech all understandable	28,4	36.3[f]	44.0[f]	51.8[d]	GM32	Balance each foot 6 seconds	41.8	47.9[e]	53.8[e]	59.7[e]
LA33	Understand 4 prepositions	30,8	37.5[d]	44.0[d]	50.7[e]						
LA34	**Name 4 colours [a]**	51,9	56.8[f]	61.5[f]	66.3[f]						
LA35	**Define 5 words [a]**	47,4	54.3[f]	61.0[d]	67.8[d]						
LA36	Know 3 adjectives	34,5	40.6[d]	46.5[d]	52.5[e]						
LA37	**Count 5 blocks [a]**	49,0	54.3[d]	59.4[d]	64.6[d]						
LA38	Opposites-2	48,5	54.0[d]	59.2[d]	64.5[d]						
LA39	**Define 7 words [a]**	59,1	66.8[f]	74.2[f]	81.8[f]						

PS=personal-social; FM=fine motor-adaptive; LA=language; GM= gross motor items
[a] Adapted test items (written in bold).
[b] The child is able to perform or pass the task soon after birth.
[c] Newly added test item removed at final consensus meeting.
[d] Item achieved at no significantly different ages it is achieved in Denver II (achieved at similar age)
[e] Item achieved at a significantly earlier age than the age it is achieved in Denver II (achieved at earlier age).
[f] Item achieved at a significantly later age than the age it is achieved in Denver II (achieved at later age).

The 90% age of milestones attainment on Denver II-Jimma significantly differed from Denver II on 42 (33.6%) items (9 PS, 6 FM, 15 LA, and 12 GM). Fifteen test items were attained at an earlier age and 27 items at a later age than they are achieved on the Denver II. The remaining 83 (66.4%) milestones were achieved at a similar age (Table 3).

2.1.4.2.3. Reliability of the Denver II-Jimma

Table 4 summarizes the results for the reliability of the Denver II-Jimma at individual test item and overall domain levels. Inter-rater reliability was excellent except for two test items which showed substantial agreement: ("PS5: work for toy", kappa= 0.74 and FM5: "follow 180 degrees", kappa=0.78). The majority (above 90%) of the test items have a substantial to excellent test-retest reliability. Only one test item (FM 8: "look for yarn", kappa= 0.33) showed unacceptable kappa values. The Denver II-Jimma also demonstrated very high intra-class correlations on all domains of development (Table 4).

2.1.4.2.4. Final consensus on Denver II-Jimma

As bottle feeding is being discouraged in line with the WHO's recommendation, it is agreed that the test item "Feed doll" should be administered without using a toy bottle. Local material "*Callee*" initially suggested to replace the object "rattle" to administer the item "work for toy" was risky for babies because it is small and could be swallowed. Hence, the adaptation was dropped. A newly added test item ("toilet going") was found difficult to perform before the age of six years and was thus eliminated. A gross motor item "Walk up steps" was not possible to assess in homes lacking steps. In such cases, care givers were asked if a child is able to walk up a steep incline or cross an elevated doorstep. Hence, the Denver II-Jimma finally evolved as a-125-test item tool with 36 (28.8%) adapted test items: 17 PS, 10 FM, 8 LA and one GM items.

Table 4 Reliability of Denver II-Jimma at item level indicated by inter-rater [a] and test re-test [b] kappa values, and at domain-level indicated by inter-rater and test-retest intra-class correlation coefficients

Reliability Measures	**PS (26 items)**	**FM (29 items)**	**LA (39 items)**	**GM (32 items)**	**Total (126 items)**
Inter-rater (kappa values)					
Excellent (0.81-1.00)	21 (80.8%) 4 (15.4%)***	24 (82.8%) 4(13.8%)***	34 (87.2%) 5(12.8%)***	27 (84.4%) 5(15.6%)***	124 (98.4%)
Substantial (0.61-0.80)	1(3.8%)	1 (3.4%)	-	-	2 (1.6%)
Acceptable (0.41-0.60)	-	-	-	-	-
Poor (<0.41)	-	-	-	-	-
Inter-rater					
(ICC) [c], [95% CI]	0.983,[0.979-0.986]	0.982, [0.978-0.985]	0.951,[0.940-0.959]	0.967,[0.961-0.973]	-
Test retest (kappa values)					
Excellent (0.81-1.00)	15 (57.7%) 4 (15.4%)***	4(13.8%) 5 (17.24%)*** 1(3.45)*	14 (35.9%) 6 (15.4%)*** 1(2.6%)**	14 (43.8%) 5 (15.6%)***	69 (54.8%)
Substantial (0.61-0.80)	5 (19.2%)	13 (44.8%)	16 (41%)	11 (34.4%)	45 (35.7%)
Acceptable (0.41-0.60)	2 (7.7%)	5 (17.24%)	2 (5.1%)	2 (6.3%)	11 (8.7%)
Poor (<0.41)	-	1 (3.45%)	-	-	1 (0.8%)
Test-retest (ICC) [d], [95% CI]	0.802, [0.721-0.859]	0.831, [0.736-0.888]	0.840, [0.773-0.887]	0.793,[0.711-0.852]	-

PS=Personal social; FM=Fine motor-adaptive; LA=Language; GM=Gross motor; ICC= intra-class correlation coefficient; CI=confidence interval.

***Kappa value not calculated but percentage of agreement is 100.

**Kappa value not calculated but percentage of agreement is 93.3.

* Kappa value not calculated but percentage of agreement is 90.91.

[a] Agreement between two measurements done independently at a time; [b] Agreement between measurements repeated at a different time.

[c] One-way random effect model is used and shows very high correlation; [d] Two-way random effect model is used and shows high correlation.

2.1.5. Discussion

In order to provide early intervention for children developmentally at risk, correct assessment of their developmental status is an essential first step. Since development is influenced by the sociocultural contexts, instrument assessing child development should take culture into account. The tools should also be psychometrically valid. While child development tools created in western cultural contexts are psychometrically valid, they may not be culturally relevant to use with African children. Many agree that culturally relevant developmental assessment tools should be either created (Vameghi R., 2009) or adapted from tools developed in other cultures (Gladstone et al., 2008; Nampijja et al., 2010). Adapting an existing tool is less expensive and more suitable to maintain construct validity of a tool across different settings.

In this study the Denver II created in the Western socio-cultural context, was adapted and standardized on Ethiopian children in Jimma town. The Denver II-Jimma evolved as a culturally relevant tool, ready to use for children from birth to six years in the multicultural and multilingual communities in the Jimma Zone, south west of Ethiopia. In the adaptation process, 36 items of the 125 in the Denver II test were modified. No test item was dropped, and this would guarantee to maintain the objectives and content validity of the original tool. Content validation was conducted by going through each test item at different meetings by the multidisciplinary research team with knowledge of local and western cultures. First, the objective of testing each Denver II test item, specific skill or competence assessed was discussed. Then the equivalence of the adapted version of the test item with the original one was examined in line with the objective, skill or competence assessed. This process was meant to maintain both content and construct validity.

Adaptation was predominantly in personal social test items. Only one gross motor item was adapted. This is consistent with other studies (Gladstone et al., 2008; D. N. Wijedasa, 2012). Personal social skills seem to be more prone to socio-cultural influences than gross motor skills.

Feasibility and reliability of all test items were ensured during the adaptation process through piloting and fine-tuning. Good inter-rater and test-retest reliabilities were demonstrated during testing at schools by kindergarten teachers, and, at home by clinical nurses indicating that the Denver II-Jimma is reliable to use at different settings by different professionals. A strong intra-class correlation across all the domains also shows good overall reliability. Similar to the Denver II (Frankenburg, Dodds, et al., 1992a), inter-rater reliability seems to be better than the test-retest reliability.

Milestones attainment on Denver II and Denver II-Jimma were compared on 90 percentile ages. Though there is no significant difference on majority (66.4%) of the test items, a clinically significant difference was observed on 42 items. Such a difference was also reported in earlier studies (Alnaquib, Frankenburg, Mirza, Yazdi, & Al-Noori, 1999; Bryant, Davies, & Newcombe, 1979; Chikvinidze et al., 2003a; Gladstone et al., 2008; Lim et al., 1994; Shapira & Harel, 1983; Solomons, 1982; D. N. Wijedasa, 2012). The difference was found for both the culture specific and the cross-cultural items. This finding of achieving milestones at different ages seems to justify the need to have separate normative standards for valid interpretation of test results from different socio-cultural contexts.

Differences are observed in the number of Denver II test items adapted in different settings. While 36 test items are adapted in the present study, only two items (personal social item "'play-pat-a-cake' and language item Baba or Mama, nonspecific') were modified while standardizing and adapting Denver test to Tbilisi (Chikvinidze et al., 2003a) children in Georgia. Only five test items (4 personal social and one language) were modified while adapting and standardizing Denver II on Sri Lankan children (D. N. Wijedasa, 2012). In Singapore, 77 Denver II items (67%) were shared with the adapted and standardized Singaporese version (Lim et al., 1994). Such findings seem to show that the number of test items needing adaptation varies in different socio-cultural contexts.

There are also differences in ages of attaining milestones in different settings. With a difference of more than 10% on 90 percentile passing age, the

Singapore differed on more than 30 items (20.1%); the Denver–Tbilisi on 25 items (24%), the Denver II-Jimma on 42 items (33.6%) with the original Denver II. A comparison of the Sri Lankan norm with the Singapore and the Denver II norms also showed a difference of more than one month in ages of attaining milestones in more than 75% of items in all domains (D. N. Wijedasa, 2012). The differences in ages of attaining milestones in the present study produced findings that are expected and consistent to earlier studies.

2.1.5.1. Strengths and limitations of the study

Taking in account that the Denver II-Jimma should be an 'ideal reference' to detect children at developmental risk, and monitor the general recovery of the child during rehabilitation, much care was spent on the standardization. Standardization therefore was done on a large sample of healthy children by excluding those with obvious disabilities and at risk during pre and perinatal stages of development. Children from comparatively very low-income families were not included for fear that such children are at higher developmental risks related to malnutrition and developmentally non-stimulating home environment. Moreover, significantly malnourished children were also excluded from the analysis since malnutrition affects development.

An important aspect of the adaptation process is the involvement of an interdisciplinary team comprising academicians and practitioners from both the Western and the local cultures. They were found instrumental in understanding both contexts while making relevant adaptations. Such a team composition was either not reported or considered in other similar studies. The study is not also without limitations. First, though the Denver II is valid and is still in use in the Western world, it was standardized 24 years ago. This standard is, however, still in use. Therefore, this study compared the data from two different time points. Second, though it is claimed that adaptation improves sensitivity (Chikvinidze et al., 2003), the Denver II-Jimma could still be a subject of limitation of the Denver II: weak specificity (Glascoe et al., 1992). With adaptation of the traditional scoring and interpretation, however, the Denver II is regarded as more suitable for children with medically complex conditions (Ware, Sloss, Chugh, & Budd, 2002), and a valid tool, particularly in assessing the language and fine motor skills of children with neurodevelopment risks (Schatz, McClellan, Puffer, Johnson, & Roberts, 2008).

2.1.5.2. Conclusion

This study demonstrated how a Western tool can be effectively adapted to a non-Western setting. With high inter-rater and test retest reliability, the Denver II-Jimma quickly assesses development of under six children, and is easy to use by first-line health workers and kindergarten teachers at home, school or health centres. Difference in milestones achievement ages on the adapted tool and on its originating Western tool shows that creating a local standard using the adapted tool is necessary for a valid interpretation of results. The study was conducted on children of diverse cultural, linguistic and ethnic communities. Hence, the result could be generalized to many other populations of Ethiopian children. However, some minor modifications may be needed in certain contexts which significantly differ from the present study setting. Future research has to examine if the tool can be used in other similar settings.

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Study 2

STUDY 2: Developmental performance of hospitalized severely acutely malnourished under-six children in low-income setting

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2.2.1. Abstract

Retrospective studies show that severe acute malnutrition (SAM) affects child development. However, to what extent SAM affects children of different ages at its acute stage is not well documented. This study was aimed at comparing the developmental performance of severely acutely malnourished children under six with that of age and gender-matched non-malnourished healthy children.

The developmental performances of 310 children with SAM (male=155, female=155); mean age=30.7 mo.; SD=15.2 mo.) admitted to the nutritional rehabilitation unit (NRU) at Jimma University's Hospital was compared with that of 310 age and gender-matched, non-malnourished healthy children (male=155, female=155; mean age=29.6 mo.; SD=15.4 mo.) living in Jimma Town in Ethiopia. Two culturally adapted tools were used: (1) the Denver II-Jimma, to assess the children's performance on personal social (PS), fine motor (FM) language (LA), gross motor (GM) skills, and (2) the Ages and Stages Questionnaires: Social-Emotional (ASQ:SE), to assess social-emotional (SE) skills. Multivariable Poisson regression analysis was conducted to compare the developmental performance scores of SAM and non-malnourished children.

For one-year-old SAM children, developmental performance on GM, FM, PS and LA is delayed by 300%, 200%, 140 % and 71.4% respectively. For three-years-old SAM children, the delay on GM is by 80%, on FM and LA by 50% each, and on PS by 28.6%. Of the skills assessed on Denver II-Jimma, GM is the most, and PS is the least affected. Younger SAM children are more affected than older ones on all the domains of development. The delay in FM, GM, LA and PS generally decreases with an increase in age. Social-emotional behaviour problems seem to be most pronounced in the very young and older age ranges. In general, SAM has a differential age effect on the different dimensions of development in children under six years of age.

2.2.2. Background

Child undernutrition, which manifests mainly as stunting, underweight, and wasting is one of the global health problems. In 2013, at least 161 million under-five children were globally stunted; 99 million were underweight; and 51 million were wasted with a higher prevalence in Asia and sub-Saharan Africa (UNICEF-WHO-The World Bank, 2014). In Ethiopia, a report in 2014 shows that 40%, 25% and 9% of under-five children were stunted, underweight and wasted respectively (Central Statistical Agency [Ethiopia], 2014). Though under-five, infant and neonatal mortality has declined from 205 deaths in 1990 to only 64 deaths per 1000 live births in 2013 (You, Hug, Chen, Wardlaw, & Newby, 2014), Ethiopia is still among the 14 countries in the world with the largest burden and highest prevalence of stunting, and among 10 countries with the highest prevalence of wasting (UNICEF, 2013b).

Studies have documented the detrimental effects of child malnutrition on growth, development, later school achievement, and health outcomes (Aboud & Alemu, 1995; Drewett et al., 2001; Sally Grantham-McGregor et al., 2007; Sally M. Grantham-McGregor, Fernald, & Sethuraman, 1999; Graves, 1976; Lowe, J.Erickson, & MacLean, 2010; Prado & Dewey, 2014; Stein, 2014; Tofail et al., 2012; Susan P Walker et al., 2007). Most of such studies focused on chronic malnutrition. Some studies addressed long-term effects of severe malnutrition using a retrospective case control study design (Bartel et al., 1978; J. R. Galler, Ramsey, Forde, Salt, & Archer, 1987; J. R. Galler et al., 1990; Janina R. Galler et al., 1987b; Hoorweg & Stanfield, 1976; Lloyd-Still, Hurwitz, Wolff, & Shwachman, 1974; Nwuga, 1977) and focused only on one or very few dimensions of development. Few studies that dealt with the short-term effects of severe acute malnutrition (Sally Grantham-McGregor, Stewart, & Schofield, 1982; Sally Grantham-McGregor, Stewart, & Powell, 1991b; S. M. Grantham-McGregor, J. M. Stewart, & R. P. Desai, 1978) compared hospitalized severely malnourished and non-malnourished control subjects or siblings. The levels of the different dimensions of development of such children have not been investigated by comparing them with that of healthy children developing in optimal conditions. Moreover, since indigenous tools for assessing child development are lacking in low-income contexts such as countries in Africa, research in the area of child development is very scarce. The very few studies conducted have used Western tools without standardizing them on local children by either translating or adapting them with little validation (Boivin et al., 1995; Drotar et al., 1999; Holding et al., 2004; Nampijja et al., 2010; Servili et al., 2010), or by dropping culture specific test items (Aboud & Alemu, 1995; Bhargava, 2000; Drewett et al., 2001; Neumann et al., 1991; Stoltzfus et al., 2001). The validity and reliability of data obtained using such tools is thus questionable. With the idea that the first three years of life is the critical period for child development, many studies focused on infants and young children of three or less years of age. Moreover, such studies have not addressed various developmental dimensions simultaneously. Hence, studies comprehensively addressing multiple dimensions of child development by including children above three years of age are scarce. Consequently, it is unclear whether or not risk factors such as severe acute malnutrition differentially affects the different dimensions of development in children under six.

In brief, in low income settings, there is a lack of more reliable and multidimensional insight into the comprehensive developmental profile of under-six children at risk such as those with severe acute malnutrition (SAM).

The aim of this study, therefore, was to compare multidimensional developmental performance of three months to six-year-old severe acute malnourished (SAM) children with non-malnourished healthy children using culturally adapted tools.

2.2.3. Methods

2.2.3.1. Study setting, design and sampling

The study was conducted in Jimma Zone, south west Ethiopia. According to the 2007 census (Central Statistical Agency - Ethiopia, 2007), Jimma Zone has 17 districts having a population of 2,486,155 (50.3% male). Majority (94.5%) live in rural areas on subsistence agriculture; 2,129,321 (85.6%) are followers of Islam. The zonal capital, Jimma Town, has a population of 120,960 (50.3% male). The majority (56,661 or 46.8%) of residents of Jimma Town are Orthodox Christians; 47,205, or 39% are Muslims, and 15,799 or 13.1% are protestant Christians. Cross-sectional data were collected from both severely acutely malnourished (SAM) and non-malnourished healthy children. SAM children admitted to hospital for treatment were recruited with a non-probability convenient sampling. Age and gender matched non-malnourished healthy children were selected purposefully from families with middle or high socio-economic status assumed to be suitable for optimal child development. The SAM and the non-malnourished groups were assessed using culturally adapted tools and compared on five different areas of child development.

2.2.3.2. Participants

2.2.3.2.1. Severe acute malnourished (SAM) children

A total of 826 SAM children were coming from nearby districts in Jimma Zone and admitted to the nutritional rehabilitation unit (NRU) at the paediatric ward of Jimma University's Specialized Referral Teaching Hospital from 8/02/2011 to 28/04/2013. Only 310 (155 males, 155 female) children (mean age=30.7 mo.; SD=15.2 mo.; range=3.1—65.7 mo.) were involved in the study (Fig.2.2.1).

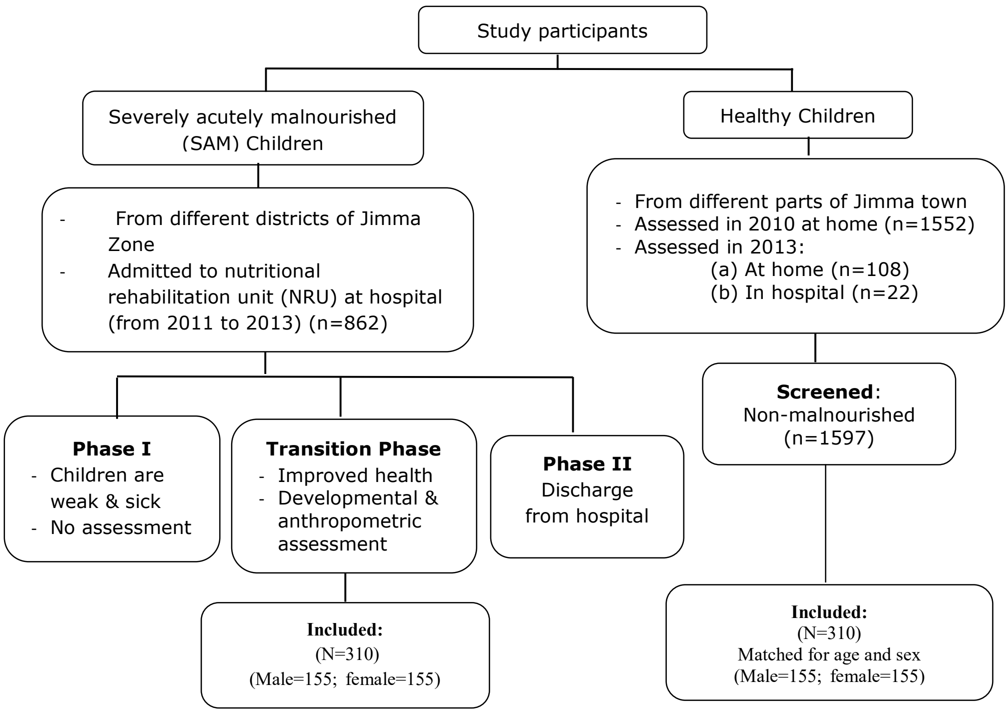


Figure 2.2.1. Selection of study participants

Inclusion criteria were based primarily on a protocol prepared by the Ethiopian Federal Ministry of Health (Chamois et al., 2007): children (a) whose wasting was severe (weight-for-height [W/H] less than 70%, National Centre for Health Statistics (NCHS) (Hamill, Drizd, Johnson, Reed, & Roche, 1977), or (b) with a low mid upper arm circumference (MUAC), i.e., MUAC less than 110 mm with a length greater than 65 cm; or, (c) having bilateral pitting oedema. Only three months to six years of age children living within accessible driving and/or walking distance in the different districts of Jimma Zone were included. In case of twins, only one child was randomly chosen. Children with obvious disabilities, mobility problems and sensory impairments (hearing and visual problems) were excluded.

Of the three phases (stabilization, transition and rehabilitation) in the treatment of SAM children (Chamois et al., 2007) developmental and anthropometric assessment were made during the transition phase. SAM patients cannot be tested during the first phase since they are without adequate appetite and /or have severe medical complications. Assessment was made when the patients had good appetite and no major medical complications.

2.2.3.2.2. Non-malnourished (healthy) children

From a total of 1682 apparently healthy children under six who belong to families with middle or higher socio-economic status in Jimma Town, 310 children were selected and matched for age and gender with the severely malnourished children. Parental socio-economic status was determined using child's access to preschool education as a proxy. The children of parents not affording payment for preschool education were excluded assuming that they belong to lower socio-economic status. A-10-point checklist was used to exclude the following potentially developmentally at-risk children: prematurely born, birth weight less than 2500 g, very tiny body at birth, instrumentally delivered, or delivered after 24 hours of labour, born with chronic health problem, sick during the first year after birth, having observable impairments affecting sight or/and hearing, or/and mobility, having a mother who was seriously sick during pregnancy. In case of twins, one child was randomly excluded. Children suspected to be malnourished were excluded using weight-for-age and MUAC z-scores in line with WHO 2006 child growth standards (WHO, 2006b).

2.2.3.2.3. Outcomes, measurements and instruments

Five areas of child development were looked into: fine motor (FM), gross motor (GM), language (LA), personal social (PS) and social-emotional (SE) skills**.** The first four were assessed using the Denver II-Jimma (Abessa et al., 2016) : a tool adapted to the Jimma context from the Denver II (Frankenburg, Dodds, et al., 1992a). No test item was dropped during the adaptation. Test item administration and raw scoring is similar as in Denver II (Frankenburg, Dobbs, et al., 1992). For each domain, the number of test items successfully performed by a child was counted.

The problems in SE competences (self-regulation, adaptive functioning, affect, compliance, autonomy, interaction with people and communication behaviours) were assessed using parent completed Ages and Stages Questionnaire: Social-Emotional (ASQ:SE) (Squires et al., 2003) adapted to the study context (unpublished). For each item, a score equals zero if no problem is reported. A total score below an age specific cut-off indicates a typical behaviour of a child, and above this cut-off indicates a presence of social-emotional problems.

Socio-demographic variables such as maternal education, socio-economic status, child sex and age were documented through a structured questionnaire because they were identified in earlier studies (Ali, Chaudry, & Naqvi, 2011; Cleland & Ginneken, 1988; Fledderjohann et al., 2014; Santos et al., 2008) as potential predictors of child developmental outcomes. Electronic digital weight scale and MUAC tape were used respectively to measure weight and MUAC of children.

2.2. 3.2.4. Data collection and testing procedure

Data were collected by five pairs of clinical nurses trained in anthropometric measurements and administrations of the ASQ:SE and Denver II-Jimma test items. The testing procedure was as follows: 1) interviewing parents or caregivers using a questionnaire on socio-demographic information, and the ASQ:SE; 2) testing the child with the Denver II-Jimma test; and, 3) finally, measuring weight and then MUAC.

2.2.3.2.5. Statistical analysis

The primary goal was to investigate whether developmental performances of severely malnourished and non-malnourished children differ. The five developmental outcomes were summarized as count scores. Hence, Poisson regression was fitted to the data, and a negative binomial regression, in case of over dispersion. The model equation $f(\mu_{Y|X}) = \beta_0 + \beta_1 X$ with a link function g(μ) is used to link between the mean of 'Y' on the left, and the fixed component on the right side of the equation as follows:

$$g(\mu) = \beta_0 + \beta_1 x_1 + \beta_2 x_2 \ldots + \beta_k x_k = x_i^T \beta$$

*Where the r*esponse *Y* has a Poisson distribution that is $y_i \sim Poisson\ (\mu_i)$ for i=1,...,N where the expected count of y_i is E(Y)=μE(Y)=μ.

As a natural fit for count variables in the Poisson or negative binomial distribution, a natural log link is used to exponentiate the linear predictors as follows:

$$\ln(\mu) = (\beta_0 + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_{3\ldots\ldots})$$

$$\mu = exp^{(\beta_0 + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_{3\ldots\ldots})}$$

where x_1, x_2 and x_3 are the covariates, or the explanatory variables in the model.

A step-wise selection procedure was employed to find the most parsimonious model. In the first step, the regression model included maternal religion, a child's gender, age and nutritional status as explanatory variables. In the second step, only the significant terms in the first step were kept and the evolutions of developmental performance with age was allowed to be curvi-linear (possibly a quadratic association). Furthermore, interactions of the child's nutritional status with maternal religion, with a child's gender and age were allowed to examine mediating effects. A significant level of 5% was used. This model building was done for all of the five developmental domains separately. The parsimonious model comprised age as both linear term and quadratic term, nutritional status and their interactions.

Ideally, the difference in developmental performance between malnourished and non-malnourished children was also corrected for maternal education and socio-economic status. Earlier studies have shown association of maternal education with a number of factors such as economic condition (Yimer, 2000) and severe malnutrition (Dereje, 2014). But the strong collinearity between these covariates makes the results of a multiple regression model including these factors together untrustworthy. Therefore, for each developmental performance, we opted to investigate three regression models, each focusing on one of these predictors at a time. Model I (as discussed above) studied the relationship between the developmental performance and the nutritional status, Model II between the developmental performance and family socio-economic status, and Model III between the developmental performance and maternal education. In line with the primary objective of the study, more attention was given to model I.

To estimate the delay in developmental performance of SAM children on the different domains of the Denver II-Jimma scale, the number of test items performed by SAM and non-malnourished children at ages three to 70 months were predicted from the regression model. The difference in age of attaining equal number of test items was calculated as an index of developmental delay. A weighted score was calculated by dividing the delay index by the age at which the non-malnourished children perform the same number of items performed by the SAM children. The weighted scores were also converted into percentages, and used for comparisons of different domains at different ages.

An index to quantify social-emotional problems was computed by subtracting the total ASQ:SE scores of the healthy children from that of SAM children at median ages on eight age groups (6, 12, 18, 23.5, 29.5, 37.5, 47.5, 59.5 months). Dividing this problem behaviour index by the respective median age resulted in a weighted index. The index was also converted into percentages. The age-specific cut-off was also subtracted from the mean score of SAM child at median age and then divided by the cut-off. This also produced an alternative standard score to determine the deviation of SAM children's score from the cut-off score. The statistical analysis was performed using STATA Software: Release 12 (StataCorp, 2011).

2.2.4. Results

2.2.4.1. Characteristics of study participants

A total of 620 (SAM: n=310; non-malnourished: n=310) children from diverse ethnic, linguistic and religious communities participated in the study (Table 1). Malnourished children (mean age =30.7 mo. and SD=15.2 mo.) are age-matched with non-malnourished children (mean age =29.6 mo. and SD=15.4 mo.). Both SAM and non-malnourished children are equally distributed across eight different age groups. Malnourished children live predominantly in the rural areas, belong to Muslim mothers and represent one dominant ethnic group (the Oromo). Majority (96%) of their mothers have primary or no education, and half (51.6%) of them reported that they belong to low-income family.

Table 1 Demographic characteristics [n(%)] of the participating children (N=620)

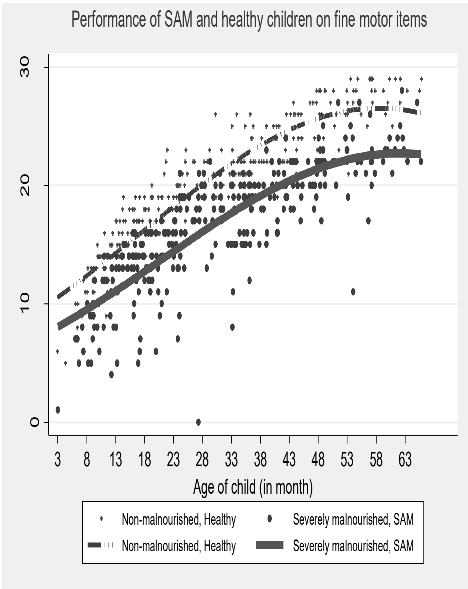
	Nutritional status			Nutritional status	
Characteristics	SAM [a]	Healthy [b]	Characteristics	SAM [a]	Healthy [b]
Sex			Ethnicity		
Male	155 (50)	155 (50)	*Amhara*	15 (4.8)	67 (21.6)
Female	155 (50)	155 (50)	*Dawuro*	3 (0.97)	38 (12.3)
Age group			*Oromo*	284 (91.6)	132 (42.6)
3-8 mo.	12 (3.9)	14 (4.5)	*Gurage*	1 (0.3)	26 (8.4)
9-14 mo.	39 (12.6)	49 (15.8)	*Keficho*	2 (0.6)	14 (4.5)
15-20 mo.	53 (17.1)	52 (16.8)	*Tigre*	0	8 (2.6)
21-26 mo.	38 (12.3)	36 (11.6)	*Wolayita*	1 (0.3)	2 (0.6)
27-32 mo.	30 (9.7)	30 (9.7)	*Yem*	3 (0.97)	0
33-41 *mo.*	59 (19)	53 (17.1)	*Other*	1 (0.3)	12 (3.9)
42-53 *mo.*	52 (16.8)	52 (16.8)	*Unknown*	0	11 (3.5)
54-65 *mo.*	27 (8.7)	24 (7.7)	Address		
Maternal education			*Dedo*	52 (16.8)	-
Illiterate	244 (78.7)	26 (8.4)	*Jimma town*	44 (14.2)	310 (100)
Primary	53 (17)	123 (39.7)	*Gomma*	16 (5.2)	-
Secondary or higher	12 (3.9)	149 (48)	*Mana*	39 (12.6)	-
Unknown	1 (0.3)	12 (3.9)	*Omonada*	20 (6.5)	-
Maternal religion			*Seka*	42 (13.5)	-
Orthodox	22 (7.1)	134 (43.2)	*Serbo*	81 (26.1)	-
Protestant	1 (0.3)	46 (14.8)	*Shabe*	10 (3.2)	-
Islam	287 (92.6)	113 (36.5)	*Others*	6 (1.9)	-
Others	0	6 (1.9)			
Unknown	0	11 (3.5)			
*SES					
Low or lower	160 (51.6)	9 (2.9)			
Middle or higher	149 (48.1)	289 (93.2)			
Missing	1 (0.3)	12 (3.9)			

SAM [a] = severely acute malnourished children; Healthy [b] = non-malnourished children; mo.= month; *SES= Family socio-economic status through self-report by the caregiver

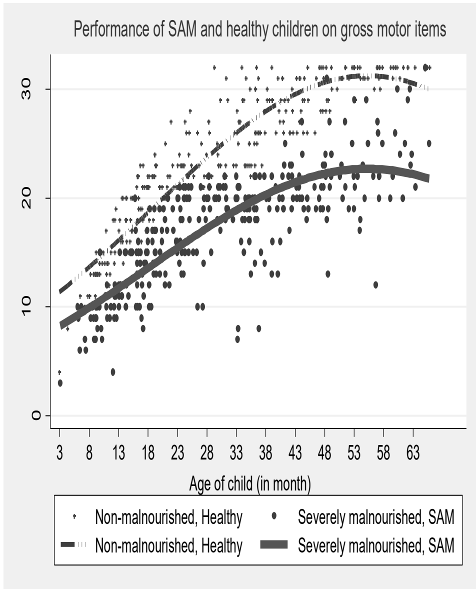
The non-malnourished group is from Jimma town, and represents diverse religious and ethnic communities with better family income. Nearly half (48%) of their mothers have secondary or higher education, and 58% of them are Christians.

2.2.4.2. Developmental performances of SAM and non-malnourished children

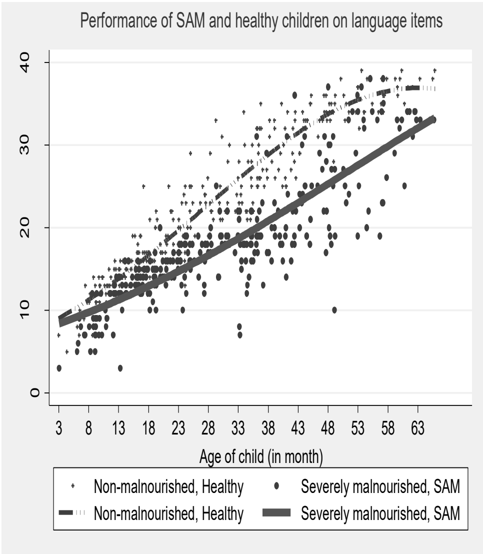
SAM children perform significantly worse than the non-malnourished children on FM, GM, LA, PS, SE. Differences in developmental performance of the severely malnourished and the non-malnourished children are graphically displayed (Fig.2.2.2.).



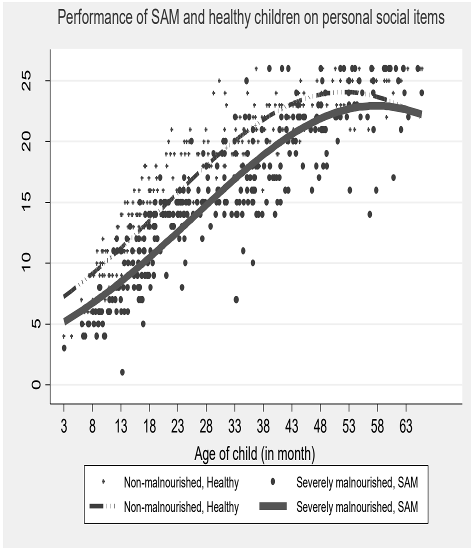
(a).



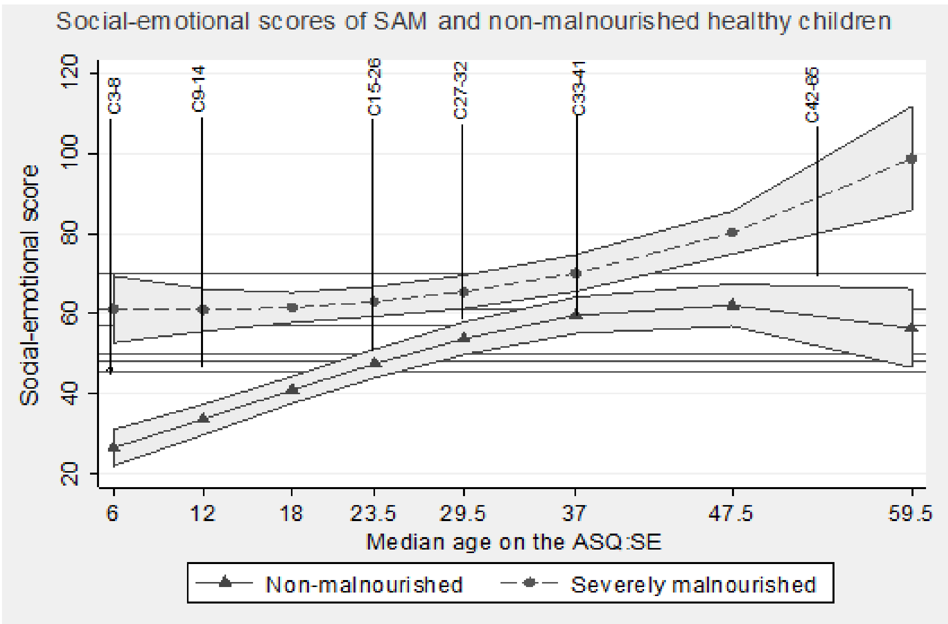
(b).



(c).



(d).



(e).

Figure 2.2.2. Effects of nutritional status on (a)fine motor, (b) gross motor, (c) language, (d) personal social and (e) social-emotional development of under-six children.

C3-8= cutoff score of 45 for children aged 3 to 8 mo.; C9-14= cutoff score of 48 for children aged 9 to 14 mo.; C15-26= cutoff score of 50 for children aged 15-26 mo.; C27-32= cutoff score of 57 for children aged 27 to 32 mo.; C33-41= cutoff score of 59 for children aged 33 to 41 mo.; C42-65= cutoff score of 70 for children aged 42 to 65 mo.; ASQ:SE= Ages and Stages Questionnaires: Social-Emotional; SAM, severe acute malnourished

Table 2 Three steps [a] multivariable predictors of performance on five domains of child development

Developmental Outcomes		Covariates				
		[d] Age	Age^2	[e] Nutri	Nutr#Age	Nutri#Age^2
[b] Fine motor	[c] IRR	1.036	0.9997	0.7556	1.002	-
	95%CI	[1.032, 1.039]	[0.9996, 0.9998]	[0.7094, 0.8047]	[1.001, 1.004]	-
	p-value	0.000	0.000	0.000	0.008	-
[b] Gross motor	[c] IRR	1.042	0.9996	0.7263	-	-
	95%CI	[1.038, 1.046]	[0.9996, 0.9997]	[0.7091, 0.7438]	-	-
	p-value	0.000	0.000	0.000	-	-
[b] Language	[c] IRR	1.050	0.9996[¥]	0.9778	0.9829	1.000[¥]
	95%CI	[1.046, 1.054]	[0.9996, 0.9997]	[0.8610, 1.110]	[0.9753, 0.9906]	[1.000, 1.000]
	p-value	0.000	0.000	0.730	0.000	0.000
[b] Personal social	[c] IRR	1.053	0.9995	0.7015	1.006	-
	95%CI	[1.049, 1.058]	[0.9994, 0.9996]	[0.6542, 0.7521]	[1.004, 1.007]	-
	p-value	0.000	0.000	0.000	0.000	-
[b] Social-emotional	[c] IRR	1.050	0.9995	3.087	0.9482	1.001[¥]
	95%CI	[1.034, 1.067]	[0.9992, 0.9997]	[2.236, 4.261]	[0.9284, 0.9683]	[1.000, 1.001]
	p-value	0.000	0.000	0.000	0.000	0.000

[¥] the estimate lies within the confidence interval when it is in five decimal digits.
[a] Model in Step I analysis comprises age, sex and nutritional status of child, maternal religion; in step II, only significant terms in step I, age as a quadratic term, interactions of nutritional status with maternal religion, with age as a linear term and as a quadratic term were added to step I model; and in step III, non-significant terms in Step II model were dropped beginning from a non-significant interaction between nutritional status and age as a quadratic term;
[b] Multivariable Poisson regression model was fitted; [c] IRR, incident rate ratio, analogous to odds ratio, is obtained by exponentiating the coefficient in the Poisson model; IRR=1 shows both the SAM and the healthy children perform equally; IRR<1 shows the SAM children (coded 1) perform less while IRR>1 shows the SAM children performed more than the healthy children (higher score on SE shows more problem behaviour); [d] age of a child (in months); Age^2, age squared.
[e] 'Nutri, nutritional status of child': severely acute malnourished, coded as 1, 'non-malnourished' coded as 0 is a reference.

2.2.4.3. Predictors of child developmental outcomes

Nutritional status has a significant effect on all five domains of child development. The differences vary depending on the age of the children on all the developmental domains except GM. This is shown by lack of interaction between age and nutritional status for GM (Table 2) even though the fitted lines within Figure 2.2.2 do not seem to be parallel since the lines are drawn from an exponentiated log scale. The malnourished and the non-malnourished children also differ from each other with respect to maternal religion, but this difference has no significant association with all the developmental outcomes. The most problematic Denver II Jimma domain for SAM children seems to be gross motor. This is observed throughout the whole age range (Table 3). The SAM children performed significantly less, $p<0.001$, (IRR= 0.7263, 95%CI [0.7091, 0.7438]. This means that on average, their performance on GM is lowered by 27.4%, 95CI, [-29.1%; -25.6%] compared to the non-malnourished children (Table 2). On the contrary, problems in performances on FM, PS, LA, and SE vary by age as shown by significant interaction between age and nutritional status (Table 2). Very young SAM children show more problems in FM, GM and PS than the older ones (Fig.2.2.3). On the social-emotional domain, they perform worse during early age and at later ages (Fig.2.2.2 and Table 4).

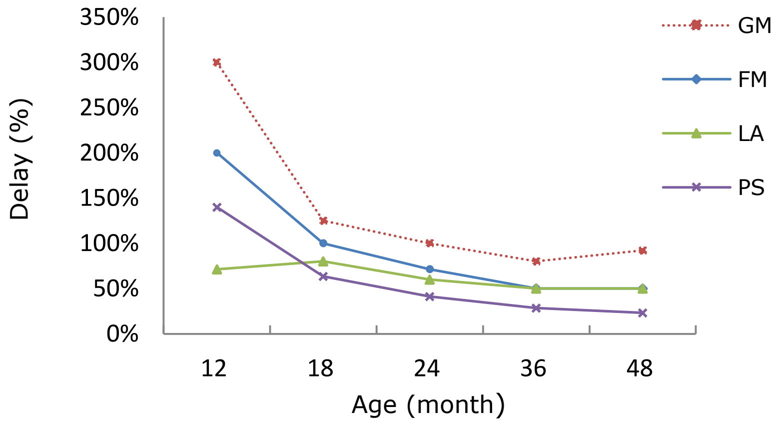


Figure 2.2.3. Developmental delay by SAM children on four domains compared to development of non-malnourished children

FM, fine motor; GM, gross motor; LA, language; mo., month; PS, personal social; SAM, severe acute malnourished

The delay in performance of SAM versus non malnourished children at different ages for GM, FM, LA and PS has been summarized (Table 3). On fine motor, for instance, a 12 month old SAM child is only capable to perform the skills of a 4-month old healthy child. This is a delay of 8 months or 200%. Very young (until 12 months) SAM children show a delay on GM by 300%, FM by 200%, and PS by 140%. The delay generally decreases with an increase in age except for gross motor. The least affected skill for children under one year of age is language (by 71.4%), but after about 18 months of age, it is the personal-social skill (Fig.2.2.3 and Table 3).

Table 3 Delay in performance of SAM versus non-malnourished children at different ages on motor, language and personal social skills

Age of SAM children	Delay (mo., %)[a] of SAM children			
	Fine Motor	Gross Motor	Language	Personal Social
12 mo.	8 mo. (200%)	9 mo. (300%)	5 mo.(71.4%)	7 mo. (140%)
18 mo.	9 mo. (100%)	10 mo.(125%)	8 mo. (80%)	7 mo. (63.6%)
24 mo.	10 mo.(71.4%)	12 mo.(100%)	9 mo. (60%)	7 mo. (41.2%)
36 mo.	12 mo. (50%)	16 mo. (80%)	12 mo. (50%)	8 mo. (28.6%)
48 mo.	16 mo. (50%)	23 mo. (92%)	16 mo. (50%)	9 mo. (23.1%)

[a] The delay in months (mo.) is obtained for each domain by calculating the number of months SAM children lag behind to perform the same number of test items performed by the non-malnourished children. The percentage of delay is calculated by the delay score of the SAM children divided by the age at which non-malnourished children perform the same number of items multiplied by hundred. On each developmental domain, delay is calculated from scores predicted for each group with Poisson regression model comprising nutritional status, age (as both linear and quadratic terms) and their interactions as covariates.

For language, the delay increases slightly before the age of two years and then decreases (Table 3). From age three onwards, it seems that both fine motor and language are equally affected. Generally, the degree of delay on the four domains decrease with an increase in age.

Table 4 Social-emotional performance of SAM versus non-malnourished children at median ages on ASQ:SE

	[a] Median age (in month)							
	6	12	18	23.5	29.5	37.5	47.5	59.5
SAM children's ASQ:SE score	61.1	60.8	61.5	62.9	65.4	70.1	80.1	98.6
[b] ASQ:SE cut-off score	45	48	50	50	57	59	70	70
[c] Deviation from cut-off (%)	16.1 (35.8%)	12.8 (26.7%)	11.5 (23%)	12.9 (25.8%)	8.4 (14.7%)	11.1 (18.6%)	10.1 (14.4%)	28.6 (40.9%)
[d] Difference: SAM versus healthy	34.5 (575%)	27.3 (227.5%)	20.6 (114.4%)	15.5 (66%)	11.6 (39.3%)	10.5 (28%)	18.1 (38.1%)	42.3 (71.1%)

[a] The median of the age ranges on the eight age groups on ASQ:SE; [b] Child's ASQ:SE score greater or equal to a cut-off score marks presence of problem behaviour; [c] Deviation score is a distance of SAM child's score from the cut-off score. Deviation percentage is calculated by dividing it by the cut-off score and then multiplying by hundred; [d] 'Difference' is calculated by referring to the healthy children (subtracting the social-emotional score of the non-malnourished children from that of SAM children); dividing the 'difference' by the median age at comparison and multiplying it by hundred gives its percentage. ASQ:SE, Ages and Stages Questionnaires: Social-Emotional; SAM, severely acutely malnourished; the ASQ:SE scores at different ages for each group is predicted from a negative binomial regression model comprising nutritional status, age (as both linear and quadratic terms) and their interactions as covariates.

The predicted count scores of SAM children on social-emotional (SE) domain are systematically above the age specific cut-off scores and the scores of the non-malnourished children (Fig.2.2.2e and Table 4). Scores above the age specific cut offs indicate the presence of social–emotional problems. This effect is more severe for SAM children in the first age category (3-8 mo.) and those in the last category (54-65 mo.) (Fig.2.2.2e).

In further analyses, the effects of maternal education and family socio-economic status on the developmental outcomes were examined separately using multivariable models comprising child's gender and age and their interactions as covariates (Table 5). The result showed a lack of a significant relationship between a child's gender and child developmental outcomes, but maternal education and family socio-economic status were found to be significant predictors in the five domains of child development.

Table 5 Multivariable predictors of developmental performance on four domains of child development [a]

Predictors	Model	Fine motor			Gross motor			Language			Personal-social			Social-Emotional		
		IRR [b]	95%CI	p-value	IRR [b]	95%CI	p-value	IRR [b]	95%CI	p-value	IRR [b]	95%CI	p-value	IRR [b]	95%CI	p-value
Sex [c]																
Female	I	[1.020]	[0.9868, 1.042]	0.093	0.9953	[0.9721, 1.019]	0.693	1.012	[0.9867, 1.038]	0.352	1.022	[0.9932, 1.051]	0.136	0.988	[0.877, 1.112]	0.838
Age*	I	1.036	[1.032, 1.040]	0.000	1.0412	[1.037, 1.046]	0.000	1.042	[1.039, 1.046]	0.000	1.053	[1.049, 1.058]	0.000	1.010	[0.999, 1.022]	0.083
Age#Age	I	0.9997	[0.9996, 0.9998]	0.000	0.9996[¥]	[0.9996, 0.9997]	0.000	0.9997¥	[0.9997, 0.9998]	0.000	0.9995	[0.9994, 0.9996]	0.000	0.999	[0.999, 1.000]	0.348
Nutritional Status [d]																
SAM**	I	0.7600	[0.7083, 0.8155]	0.000	0.7148	[0.6692, 0.7633]	0.000	0.7620	[0.7128, 0.8146]	0.000	0.6990	[0.6492, 0.7527]	0.000	1.724	[1.415, 2.100]	0.000
SAM # Female	I	0.9880	[0.9445, 1.034]	0.601	1.020	[0.9720, 1.069]	0.427	0.9967	[0.9449, 1.051]	0.905	1.004	[0.9555, 1.056]	0.865	0.919	[0.7892, 1.070]	0.272
SAM#Age	I	1.002	[1.001, 1.004]	0.008	1.000	[0.9986, 1.002]	0.822	1.000	[0.9985, 1.002]	0.921	1.006	[1.004, 1.007]	0.000	0.995	[0.9901, 1.000]	0.065
Sex [c]																
Female	II	1.014	[0.9843, 1.045]	0.353	1.000	[0.9648, 1.037]	0.988	1.024	[0.9871, 1.061]	0.208	1.018	[0.9867, 1.050]	0.265	0.910	[0.824, 1.006]	0.065
Age	II	1.035	[1.031, 1.039]	0.000	1.040	[1.035, 1.045]	0.000	1.041	[1.036, 1.046]	0.000	1.054	[1.049, 1.058]	0.000	1.010	[0.998, 1.022]	0.115
Age#Age	II	0.9997[¥]	[0.9997, 0.9998]	0.000	0.9997[¥]	[0.9995, 0.9997]	0.000	0.9997[¥]	[0.9997, 0.9998]	0.000	0.9995[¥]	[0.9995, 0.9996]	0.000	0.999	[0.999, 1.000]	0.235
SES[e]																
Low ***	II	0.7832	[0.7110, 0.8626]	0.000	0.7447	[0.6763, 0.8200]	0.000	0.8294	[0.7588, 0.9065]	0.000	.7154	[0.6531, 0.7835]	0.000	1.332	[1.082, 1.639]	0.007
Low# Female	II	1.004	[0.9492 1.063]	0.877	1.035	[0.9658, 1.109]	0.329	0.9698	[0.9020, 1.043]	0.407	1.032	[0.9735, 1.095]	0.287	1.072	[0.9197, 1.251]	0.372
Low# Age	II	1.003	[1.001, 1.005]	0.007	1.002	[0.9992, 1.004]	0.189	1.000	[0.9983, 1.003]	0.692	1.005	[1.003, 1.008]	0.000	0.999	[0.993, 1.004]	0.581
Sex[c]																
Female	III	1.019	[0.9901, 1.049]	0.198	0.9867	[0.9543, 1.020]	0.431	1.003	[0.9710, 1.036]	0.868	1.023	[0.9924, 1.054]	0.144	0.898	[0.801, 1.007]	0.065
Age	III	1.037	[1.033 1.041]	0.000	1.044	[1.039, 1.049]	0.000	1.044	[1.040, 1.049]	0.000	1.055	1.050, 1.060	0.000	1.007	[0.995, 1.019]	0.245
Age#Age	III	0.9997[¥]	[0.9996, 0.9997]	0.000	0.9996[¥]	[0.9996, 0.9997]	0.000	0.9997	[0.9996, 0.9998]	0.000	0.9995	[0.9994, 0.9996]	0.000	0.999	[0.999, 1.000]	0.557
Maternal Education[f]																
Illiterate	III	0.8290	[0.7648, 0.8986]	0.000	0.8052	[0.7420, 0.8738]	0.000	0.8031	[0.7465, 0.8640]	0.000	0.7410	[0.6845, 0.8021]	0.000	1.443	[1.177, 1.769]	0.000
Illiterates # female	III	0.9801	[0.9321, 1.031]	0.433	1.037	[0.9797, 1.098]	0.209	1.019	[0.9592, 1.083]	0.537	0.9947	[0.9434, 1.049]	0.845	1.093	[0.9385, 1.272]	0.253
Illiterate # Age	III	1.001	[0.9991, 1.003]	0.292	0.9984	[0.9964, 1.000]	0.097	0.9995	[0.9977, 1.001]	0.596	1.004	[1.003, 1.006]	0.000	0.997	[0.9917, 1.002]	0.273

Age*, age of a child (in months); SAM**, severe acute malnourished; SES, socio-economic status; Low***, very low/ low SES versus Middle/ High SES,
[¥] lies within the confidence interval range with five decimal digits. [A] Multivariable Poisson regression model was fitted; [b] IRR, Incident rate ratio, is analogous to odds ratio and is obtained by exponentiating the coefficient in the Poisson model. Model I:covariates are nutritional status, sex, age, age#age, interactions of nutritional status with age and with child's sex; Model II: covariates in model II are socio-economic status, sex, age, age#age, interactions of socio-economic status with age and with child's sex; Model III: covariates in model III are educational status, sex, age, age#age, interactions of educational status with age and with child's sex;[c] 'male' is a reference; [d] 'non-malnourished' is a reference; [e] 'middle / high' is a reference; [f] 'Primary or above primary' is a reference.

2.2.5. Discussion

Though the first three years are generally considered very critical, some years later are also very much crucial for children's holistic development. Yet most recent studies on developmental effects of severe acute malnutrition focused mainly on young children not older than 24 months of age. No study has concurrently addressed and compared various developmental dimensions among SAM children of different ages, particularly during its acute stage. Consequently, much is not known about the degree to which the different dimensions of child development are impaired during the acute stage of SAM in children under six years of age.

The present study examined the extent to which developmental performance is affected on five domains of development in SAM children three months to six years of age. Severely acutely malnourished children performed worse on personal-social, fine motor, language, gross motor skills and social-emotional competences compared to age and sex-matched non-malnourished healthy children. More specifically the study revealed that 1) motor skills are the most but personal social are the least affected domains assessed on the Denver II-Jimma, and, 2) there is a differential effect of age on all the domains except on gross motor development of SAM children under six years of age.

Earlier studies compared the development of hospitalized SAM children with protein energy malnutrition with hospitalized non-malnourished control children of other illnesses. The malnourished children were markedly behind the controls (Sally Grantham-McGregor et al., 1982). A review of earlier studies also indicated that all developmental levels are extremely low in the acute stage and generally improve during recovery (Sally Grantham-McGregor, 1995). Our study is consistent with earlier studies which showed that SAM negatively affects motor skills (Janina R. Galler et al., 1987b; Hoorweg & Stanfield, 1976). Earlier studies, however, did not specify the areas of development worst or least affected. The present study reveals that the motor skills in general, and the gross motor in particular, are more seriously affected than the language and the personal social skills of SAM children. In fact, more severe effects on motor skills (gross) is expected since severe acute malnutrition reduces muscle mass. Muscle atrophy could reduce a child's physical activity and deter further explorations and interactions with environment. This might in turn hamper not only the development in the gross motor but also in the fine motor, the personal social and the language skills.

It is now known that the effect of SAM at early life of a child is sustained to later ages. Children with histories of either marasmus or kwashiorkor during their first year of life (Janina R Galler et al., 1987; J. R. Galler et al., 1990; Nwuga, 1977) scored at later ages significantly lower on national high school examination (J. R. Galler et al., 1990), intellectual performance (Janina R Galler et al., 1987; Hoorweg & Stanfield, 1976; Nwuga, 1977) than healthy children. Adults who had experienced an episode of moderate to severe protein-energy malnutrition during the first year of life scored significantly lower than the healthy controls on measures of cognitive flexibility and concept formation, as well as initiation, verbal fluency, working memory, processing speed, and visuospatial integration (Waber et al., 2014).

Our study shows that the degree of developmental lag in SAM children during the acute stage varies depending on the child's age. Age related effects of SAM on child development have been documented in some retrospective studies. For instance, there was a lack of significant difference on psychomotor performance between a group of children aged from 6 to 12, who suffered from kwashiorkor during infancy and control groups having no infantile malnutrition (Bartel et al., 1978). Similarly, a study compared children admitted to hospital with undernutrition during the first year of life. Three to four years later, the mean developmental quotient of children treated in the first four months of life, and the control ones was similar. However, there was a difference in the developmental quotient of the control and those treated for undernutrition after four months of age (Chase & Martin, 1970). Another study compared subjects of 2 to 21 years of age, who had been severely malnourished and hospitalized during the first six months with control siblings on intellectual performance, sensory motor abilities and social adaptation. No significant difference was found for the older subjects. It was argued that the significant effect of infantile malnutrition prevails only in children aged between 2 to 5 years following their episode of malnutrition, and that there is no significant difference after the age of 5 years (Lloyd-Still et al., 1974).

Our study also shows that hospitalized SAM children have more social-emotional problems than the non-malnourished healthy children. Such behaviour problems during an acute episode may persist to later life. That has been shown in school age children with histories of malnutrition during early childhood. They showed greater behavioural problems than matched controls and, to a lesser extent, than siblings (Sally Grantham-McGregor, 1995). Similarly, elevated conduct problems (J. R. Galler et al., 2012) and depressive symptoms (J. Galler et al., 2010) were reported in youth with histories of protein-energy malnutrition during the first year of life.

2.2.5.1. Strengths and limitations of the study

The study shows the extent to which SAM children admitted to hospital for treatment are delayed in different dimensions of development compared to non-malnourished healthy children. It also depicts the magnitude of the delays on children of different ages. Interpreting our results, however, has to take the following drawbacks into account. Majority of the SAM children came from illiterate, low income and Muslim families living in rural areas and were assessed while they were in hospital. On the other hand, the non-malnourished children come from family with better socioeconomic status and mostly literate mothers of various religious backgrounds. They live in Jimma town and were assessed mostly at home setting. As this study did not control for the effect of hospitalization, the result may not show the developmental profiles of SAM children in non-hospital settings.

2.2.5.2. Conclusions

The study reveals that the developmental performance of SAM children is seriously affected during the acute stage. This effect is multidimensional and age-dependent. Hence rehabilitation of SAM children should be multi-dimensional, age-specific and focus on strengthening of motor skills during early age. Interventions at health institution have to transcend the mere goal of achieving growth and survival as prime measures of successful health outcomes and include development as an important component as well. Future research has to examine the effect of intervention on different dimensions of development among children of different ages.

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Study 3

STUDY 3: The effect of play-based family-centered psychomotor/psychosocial stimulation on the development of severely acutely malnourished children under six in a low-income setting: a randomized controlled trial

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2.3.1. Abstract

The World Health Organization (WHO) recommends incorporating psychosocial stimulation into the management of severe acute malnutrition (SAM). However, there is little evidence about the effectiveness of these interventions for SAM children, particularly when serious food shortages and lack of a balanced diet prevail. The objective of this study was to examine whether family-based psychomotor/psychosocial stimulation in a low-income setting improves the development, linear growth, and nutritional outcomes in children with SAM.

Children with SAM (N=339) admitted for treatment to the Jimma University Specialized Hospital, Ethiopia, were randomized to a control (n=170) or intervention (n=169) group. Both groups received routine medical care and nutritional treatment at the hospital. The intervention group additionally received play-based psychomotor/psychosocial stimulation during their hospital stay, and at home for six months after being discharged from hospital. The fine motor (FM) and gross motor (GM) functions, language (LA) and personal-social (PS) skills of the children were assessed using adapted Denver II, the social-emotional (SE) behaviour was assessed using adapted Ages and Stages Questionnaires: Social-Emotional, and the linear growth and nutritional status were determined through anthropometric assessments. All outcomes were assessed before the intervention, upon discharge from hospital, and six months after discharge (as end-line). The overtime changes of these outcomes measured in both groups were compared using Generalized Estimating Equations.

The intervention group improved significantly on GM during hospital follow-up on average by 0.88 points ($p<0.001$, effect size=0.26 SD). On FM functions it improved during home based follow-up on average by 0.85 points ($p=0.023$, effect size= 0.15 SD), and during the whole follow-up period by 1.09 points ($p=0.001$, effect size= 0.22 SD). The effect size, however, is small. Both young and older children benefited similarly from the treatment. The intervention enhanced improvement in gross motor functions when combined with standard nutrient-rich diets available during hospital-based follow-up. It improved the fine motor functions, even when such standard dietary care is not available during the home follow-up. The intervention did not contribute significantly to linear growth and nutritional outcomes.

2.3.2. Background

Malnutrition is one of the global challenges to children's health. In 2015, worldwide 156 million children under five were stunted, 50 million were wasted, and 42 million overweight (WHO, 2016). In low-income countries in Africa and Asia, the prevalence of malnutrition is higher. In Ethiopia for example, it is estimated that 38% of children under five are stunted, 24% are underweight and 10% wasted (Central Statistical Agency [Ethiopia], 2016). For many children, the problem already starts during intrauterine life. Poor nutrition during intrauterine life and the child's early years leads to profound and varied effects such as delayed physical growth, impaired motor and cognitive development resulting in lower IQ, more behavioural problems and deficient social skills at school age, decreased attention, deficient learning, and lower educational achievement (Heaver, 2005; Martorell, 1997; Martorell & Nguyen, 2010; Prado & Dewey, 2014; Roseboom et al., 2011). Such negative consequences, however, can be ameliorated through appropriate interventions.

Providing adequate nutrition, early psychosocial stimulation at home, appropriate preschool experiences, and learning opportunities could substantially increase cognitive development of children (Santos et al., 2008) and contribute to longer-term gains in human capital (Black et al., 2013). Reviews of studies on nutrition and stimulation for malnourished children in general (Aboud & Yousafzai, 2015; Sally M. Grantham-McGregor, Fernald, Kagawa, & Walker, 2014) and for the severely acutely malnourished ones in particular (Daniel et al., 2017) has shown that supplementing dietary rehabilitation with psychosocial stimulation can potentially reduce the adverse effects of undernutrition and improve developmental outcomes. The World Health Organization (WHO) already recommends using psychomotor/psychosocial stimulation for children in severe food shortage situations (WHO, 2006a) and those receiving treatment for severe acute malnutrition (SAM) (Ashworth, Khanum, Jackson, & Schofield, 2003; WHO, 1999, 2006a, 2013). The recommendation has a dual objective: to help recover the psychomotor/psychosocial deficit, and stimulate the SAM children to regain their appetite more quickly and gain weight faster. It assumes that integrating the two treatments would have synergistic effects (B. Nahar et al., 2009; Baitun

Nahar, Hossain, Hamadani, Ahmed, Grantham-McGregor, & Persson, 2012). However, the evidence for this comes mainly from two studies; one uses a non-randomized design with mixed outcomes.

Though the WHO recommends clinical discharge with shorter hospital admission periods followed by home-based care (WHO, 2013), providing strict dietary rehabilitation at some home settings is also hardly possible, especially in remote and inaccessible rural areas. As most SAM children come from poor families, they return to the same poor home situation. Though ready-to-use-therapeutic food (RUTF) can be used effectively at home, children living in remote rural areas far from health centres rarely get adequate supplies of RUTF. Thus, little is known about how much psychomotor/psychosocial stimulation benefits SAM children living in settings where not even a basic diet for survival is ensured, let alone essential dietary nutrients. Moreover, since many stimulation studies have so far focused on children less than 24 months of age, much is unknown with regard to older children. Above all, the evidence supporting the recommendation of psychosocial stimulation for children with SAM is inadequate, and has been criticized for being low in quality across important outcomes (Daniel et al., 2017). Therefore, further studies are needed in different low-income settings in order to identify the best strategies to support parents in caring for their young children (Baitun Nahar, Hossain, Hamadani, Ahmed, Grantham-McGregor, & Persson1, 2012). This study was aimed at examining the effect of play-based stimulation on the development, linear growth, and nutritional outcomes during hospital and home-based treatment of SAM children under six years of age in the low-income context of Jimma Zone, South West Ethiopia. The primary outcomes were developmental performances in the form of *fine motor* (FM) functions (such as picking things up between finger and thumb, or grasping and drawing) and *gross motor* (GM) functions (such as using arms, legs, feet, or entire body for crawling, running, and jumping), *language* (LA) and *personal-social (PS)* skills (such as smiling, self-feeding, helping, and playing with others) and *social-emotional behaviours* (SE) (such as autonomy, adaptive functioning, affect, compliance, communications, interaction with people, and self-regulation) The secondary outcomes were height/length-for-age z-score (HAZ), mid-upper-arm circumference z-score (MUACZ), weight-for-age z-score (WAZ), weight-for-height z-score (WHZ) or body-mass index-for-age z-score (BAZ) at discharge from hospital and after six months of follow-up at home. The anthropometric Z-scores were calculated for each child using WHO Anthro and AnthroPlus (WHO, 2011).

2.3.3. Method

2.3.3.1. Study design and subjects

A longitudinal intervention study was conducted on SAM children admitted to the nutrition rehabilitation unit (NRU) of the Jimma University Specialized Referral Teaching Hospital, South West Ethiopia. With a randomized, single blind, parallel group trial design, eligible participants were assigned to a control or an intervention group. Data collection occurred between 8th February 2011 and 19th November 2013. The study was held up due to a delay in the adaptation process of the tools used for data collection, and it took longer than planned to enrol an adequate number of eligible participants within accessible distances for follow-up. Admission to and discharge from the NRU were based on the WHO guidelines adapted by the Ethiopian Ministry of Health for the treatment of SAM children (Chamois et al., 2007). In a small number of cases, however, patients were discharged earlier in order to free up treatment space for new, more severe patients. SAM children between 6 and 60 months of age who fulfilled the following criteria were included: weight for height or weight for length less than 70% of the median on National Centre for Health Statistics (Hamill et al., 1977) of USA; or mid upper arm circumference (MUAC) < 110 mm with a length > 65 cm; or, having bilateral pitting oedema and having no medical complications (at Transition Phase i.e., Phase II). SAM children who were completely deaf or blind, who had complications hindering mobility for play, whose primary caregiver could not provide stimulation due to physical or mental disability were excluded from the study. Only one child was randomly selected from a family with more SAM children. Children from inaccessible areas and far distances (more than a 50 km radius of Jimma Town) were also excluded.

2.3.3.2. Sample size

The study was intended to detect a 5% difference in developmental performance ratio score between the control and the intervention groups after 6 months of follow-up. The performance ratio is the ratio of the number of test items a child performed successfully to the number of items he/she was expected to perform for his/her age. These numbers were determined in line with the test item administration and scoring guidelines presented in Denver II (Frankenburg, Dobbs, et al., 1992; W. K. Frankenburg, J. B. Dodds, P. Archer, H. Shapiro, & B. Bresnick, 1992b). A power of 80% was specified at a 5% significance level, assuming a 20% loss to follow-up. Estimates of the variance in developmental performance ratio scores, to be used in the power calculations, were obtained from cross-sectional data of 22 non-malnourished, healthy children (36-69 months of age; mean ± SD =51.4 ± 8.2) (Snijers, 2010). Of the four outcomes assessed using Denver II, the mean score of language (1.05 ± 0.14) was used since it was the developmental outcome with the highest variance. Accordingly, a sample of 136 SAM children in each group was expected to sufficiently power the study. However, the statistical power computed from the cross-sectional data is insufficient to power the group*time interaction effect examined in the longitudinal data set. Ideally, a pilot study or an established literature is needed to determine a more accurate sample size. The present study lacks either of the two, and is a sort of 'hypothesis generating type'. An interim analysis showed a larger variance in developmental performance scores for SAM children than for non-malnourished healthy children. Hence, we recruited 25% more children to each arm of the study to increase the sample size.

2.3.3.3. Randomization and blinding

Eligible children were randomized using computer-generated codes and allocated to the control (n=170) and intervention (n=169) groups. This was done every week by the researcher coordinating the study. Allocation concealment was ensured as the researcher had no physical access to the children.

Testers, who did not know whether a child belonged to the control or the intervention group, assessed the children in a separate room; intervention nurses worked in a separate play room which was accessible only for the intervention children and their caregivers (parents, grandparents and siblings).

2.3.3.4. The intervention

2.3.3.4.1. Play facility and intervention nurses

Prior to the start of the intervention, an appropriate infrastructure for psychomotor and psychosocial play activities was set up at the paediatric ward of Jimma University's Specialized Referral Teaching Hospital. A playroom and a playground were installed and furnished with basic facilities for engaging the SAM children in play-based motor, language, and personal-social activities. Three female clinical nurses, who were not members of the hospital staff, were trained as intervention nurses to stimulate the SAM children directly and also to transfer skills to caregivers on how to stimulate the SAM child through play activities. The intervention nurses received one week of training in the theory of child development, and one month of intensive practice in implementing developmental stimulations.

2.3.3.4.2. Stimulation phases and activities

The intervention was offered in two phases: in-patient and out-patient. The first, or in-patient phase was provided in the hospital between the Transition Phase and the discharge from the hospital. Two types of sessions were offered: individual sessions in the playroom and group sessions on the playground. A minimum of 8-10 play sessions lasting for about 20-40 minutes each were planned to be held in the presence of the caregiver in the playroom only, or both in the playroom and the playground, depending on the age and health status of the child. The intervention included auditory, tactile and visual stimulation, hand-eye coordination, and different types of sensory-motor training that included fine and gross motor activities. The guiding principle was enhancing a child's holistic development—cognitive, emotional, language physical, and social—in an integrated manner by using age-appropriate play materials, cultural tools, and resources with the caregivers playing the crucial role of mediation (Bronfenbrenner, 1970; Roley, Mailloux, Miller-Kuhaneck, & Glennon, 2007; Vygotsky, 1978). By attending play sessions, caregivers were trained through demonstration and active engagement on how to stimulate a child. Moreover, they received information on childcare and feeding and their importance for the development and growth of children. Simple play materials such as balls, picture cards, and animal-shaped toys were used to engage children in different age-appropriate activities that contribute to cognitive, emotional, language, physical, and social development.

The out-patient phase of the intervention occurred at home after discharge from the hospital. The standard criteria for discharge are for the SAM child to attain W/L>=85% or W/H>=85% on more than one occasion, and to have had no oedema for 10 days. In addition to the play materials offered on discharge, new play material was offered during each of the three planned home visits over a six-month follow-up. Three home visits (in the 3rd, 7th and 13th week) were made during this period to provide further stimulation to the SAM child and empower the caregivers of the SAM child. Empowerment of the caregivers included training on how to stimulate the SAM child, and further improvement of the mothers' and other family members' knowledge of childcare and feeding, proper nutrition, and stimulation. The family members were encouraged to show affection to the SAM child, be responsive to their cues, interact with them using the resources available at home and the simple play materials offered to them. The intervention utilized ideas from the Mediational Intervention for Sensitizing Caregivers program (Klein, 1987, 1991, 1996) and mediated learning experiences (Reuven Feuerstein, Klein, & Tannenbaum, 1999). The key issue in the intervention was enhancing interactions between the caregivers and the target child through play, guided by a principle of Safety, Enjoyment and Stimulation. Different supervisors participated in home visits to ensure that the intervention nurses could work in a qualitative way with the target child (check whether the child had been using play materials given to him/her and had been taking part in interactive play) and the caregivers (providing information/feedback and education on childcare, feeding and stimulation, and demonstrating how to use the new play materials offered to child). At each home visit, the play leaders first ensured that the child was using the play materials offered to him/her in line with his/her age. Educational play materials carefully selected by child therapists were given to the children, taking in account the following three age categories: six months to two years, two to four years, and four to six years. The child and caregiver (including family members and child's playmates in the neighbourhood) were then introduced to techniques of play using the newly provided play materials, taking into account the level of the developmental status of the child. The mothers were encouraged to use additional local materials besides the commercial toys provided by the intervention nurses. Toys such as 'African Family' and 'African Animals', picture cards, cubes, acrobats and balls were provided for each child. Siblings and peers in the neighbourhood were also encouraged to play with the target child. Some home visits were not conducted exactly on the scheduled date, and some visits were cancelled during the rainy season, thereby reducing the total number of home visits to less than the three planned moments. Some visits were made in the absence of the mother, but a caregiver was available at home. On the last home visit, the intervention nurses interviewed the caregivers using a structured questionnaire. This aimed to provide information on the progress of the child, the adherence of the parents to advice about offering home-based stimulation, and the major challenges they had encountered.

The control children received routine medical care and dietary treatment offered at the nutritional rehabilitation unit of the hospital. Although they had access to facilities in the playground, they had no access to the playroom and were not provided with stimulation and play materials. Both groups received standard formula diets (F-75, F-100, or ready-to-use therapeutic food) that contain vitamin A, folic acid, iron and all the other nutrients (potassium, magnesium and zinc) required to treat a malnourished child. F-75 and F100, or ready-to-use therapeutic food (RUTF) were used for in-patient care. F-75 (75 kcal or 315 kJ/100 mL) is a therapeutic milk used only during the initial phase of the treatment (Phase 1), whereas F-100 (100 kcal or 420kJ/100 mL) is a therapeutic milk used during the rehabilitation phase (Transition Phase and Phase 2) of the treatment. Whenever patients have a good appetite and no major medical complications, they enter Phase 2, when they are given RUTF (used in both in-patient and out-patient settings) or F100 and iron (used in in-patient settings only) according to look-up tables. On discharge, some packets of RUTF are given for home intake. After returning home, the SAM child is taken by a caregiver to a nearby therapeutic feeding centre or health centre, where registration is conducted and the child gets a Unique SAM ID number. The SAM child is followed using an individual follow-up chart and given RUTF periodically. It is advised that the SAM child is enrolled in a Supplementary Feeding Programme and given nutritional support for another 4 months.

2.3.3.5. Outcomes and measurements

2.3.3.5.1. Developmental performance

The primary outcomes of the study were the SAM children's developmental scores in FM, GM, LA, PS and SE.

Performances in FM, GM, LA and PS were assessed using the Denver II-Jimma (Abessa et al., 2016), a culturally adapted and standardized screening tool to assess the development of children under six years of age in the Jimma zone of Ethiopia. It was created by adapting 36 of the 125 test items of the Denver II child development screening test. It has an excellent inter-rater on 123 (98%) items and substantial to excellent test-retest reliability on 119 (91%) items (Abessa et al., 2016). The Denver II-Jimma comprises a total of 125 test items across the four domains. It was adapted and standardized on 1597 healthy children 4 days to 70.6 months of age. The 25, 50, 75 and 90 percentile passing ages were determined for each test item as milestones. The number of test items that a child has successfully performed (passed) is described as the performance score. Most Denver II-Jimma test items assess the performance of a child through direct observation, while a few use parental reports.

Child's problems in SE competences (self-regulation, adaptive functioning, affect, compliance, autonomy, interaction with people and communication behaviours) were assessed using the parent-completed Ages and Stages Questionnaire: Social-Emotional (ASQ:SE), adapted to the study context (unpublished) through a collaboration between a European child psychiatrist and two local academics: a psychologist and a special educator. The adapted items were translated into two local languages, piloted and amended before use. Through a semi-structured interview with a caregiver, the social-emotional behaviour of a target child was assessed on different items. The score on each item is as follows: a score of 0 indicates a normal behaviour (the absence or rarely happening of a problem behaviour); a score of 5 indicates the presence of a problem behaviour; 10 is a problem behaviour with more frequent occurrence; 15

is a problem behaviour which is a concern for the caregiver. A child's total behaviour score is obtained by adding up item-specific scores.

2.3.3.5.2. Growth and nutritional status

The secondary outcomes were linear growth, quantified by HAZ, and nutritional status, determined using MUACZ score, WAZ and WHZ for children below 60 months of age, and BAZ for children 60 or more months of age.

The child's height, weight, and MUAC were measured using a stadiometer/length-mat, calibrated digital weight scale, and MUAC tape respectively, following standard procedures (WHO Expert Committee, 1995). At each test moment, anthropometric measurements were repeated. If different values were obtained, a third measure was taken and their average was used to calculate z-scores based on WHO standards (WHO, 2011).

Developmental performance, growth and nutritional status were measured at the hospital before the intervention (as baseline), on discharge, and at home six month after discharge from hospital (end-line).

2.3.3.5.3. Socio-demographic information

Socio-demographic information was collected using a structured questionnaire. The study caregivers were also requested to provide information on the socio-demographics of the mother and child.

2.3.3.5.4. Follow-up information

During each home visit, the health and dietary condition of the intervention child, and the adherence of caregivers to run the home-based stimulation sessions were documented using a structured questionnaire. Some data on factors assumed to be affecting the performances within the intervention SAM children were gathered. Information collected include caregivers' feelings about the general health condition of the intervention SAM child, family support and engagement in the psychosocial stimulation service, the child's access to nearby health centres after discharge from hospital, the and availability of RUTF. Caregivers were asked to give their subjective rating (always, sometimes, rarely and never at all) on how often the child was getting RUTF, and whether the family provides specially prepared food for the SAM child.

2.3.3.5.5. Assessment procedure

After informed consent was obtained from the caregivers, developmental and anthropometric assessments were made during the Transition Phase of the nutritional treatment. Caregivers were first interviewed to complete the questionnaire on socio-demographic information. Then the child's development was assessed: first the ASQ:SE, followed by the Denver II-Jimma test. Lastly, anthropometric measurements were made in the following order: weight, MUAC, and length or height.

Five clinical test nurses were initially trained in anthropometric measurements and the administration of ASQ:SE and Denver II-Jimma test items. However, two who were not employed as hospital staff, and took part in data collection during adaptation and standardization of the Denver II-Jimma, collected 74% of the baseline, 81% of the discharge and 99% of the exit data. The testers did not know to which treatment group a child was allocated, though there was sometimes a possibility to guess during an exit testing whether a child had been visited during follow-up (which was the case only for the intervention children).

2.3.3.6. Statistical analysis

The developmental outcomes were summarized in terms of count scores as described earlier. These scores were entered into statistical models as continuous outcomes. Anthropometric outcomes were summarized in terms of continuous z-scores. Independent two samples t-test (for the count and the continuous data) and chi-square test (for categorical data) were used to compare the baseline characteristics of the: 1) control and intervention groups and, 2) children who completed the follow-up period and children lost to follow up.

For each outcome, every child (ideally) contributed three measurements: one at baseline, one at discharge, and one at the end of follow-up. A generalized estimating equations (GEE) model (a model more suitable to use with count outcomes [the case of our data] which violate the assumptions of normality distribution) with an intention-to-treat approach was used to account for the longitudinal design. The working variance-covariance matrix was an unstructured matrix, except the personal-social outcome, for which an exchangeable structure was specified. The general equation for the GEE model used is:

$$g\left(E\left[Y_{ij}\middle|x_{ij}\right]\right) = \acute{x}_{ij}\beta$$

where x_{ij} is a p times 1 vector of covariates; β consists of the p regression parameters of interest; $g(.)$ is the link function, and Y_{ij} denotes the jth outcome (for $j = 1, \ldots, J$) for the ith subject (for $i = 1, \ldots, N$); the link function $g(a) = a$ [identity] is used here since the response variable is modelled as a continuous score with a Gaussian conditional distribution.

The GEE estimates the average effect over the entire sample. The betas in the GEE model tell about the effect of a one unit change in covariates *on the average of the responses* of *the entire sample,* not *of a particular participant.*

The primary analysis aimed to: 1) examine the change in developmental outcomes during the hospital-based follow-up (from baseline to discharge) and during the home-based follow-up (discharge to end-line), and 2) test for possible group differences in these over time changes. Therefore, the statistical model included a common intercept for the control and intervention group, and fixed effects for time, group, and their interaction. The time variable in this model is a 3-level variable (i.e. baseline, discharge and end-line). No other explanatory variables were included. Effect sizes were calculated from the GEE models by transforming the intervention effects for each outcome into standardized scores. The length of stay in the hospital (in-patient phase) and the interval within the three testing moments were not controlled for by the study design. Consequently, measurements were not taken at fixed time intervals. Therefore, the basic analysis was complemented with an analysis considering a continuous timescale. The hospital-based and the home-based follow-up periods were merged into a continuous time variable containing the number of days in the study. The time variable was used in a GEE model, where a group-specific curvilinear evolution over time was allowed.

Separate analysis was conducted for each of the primary outcomes and no multiple testing correction adjustments were made. For each outcome, the model was expanded with explanatory variables: child's sex and baseline age, baseline developmental score, and baseline WAZ or baseline MUACZ scores (for primary outcomes), and baseline anthropometric z-scores (for secondary outcomes). Variables which differed significantly between the two groups at baseline were included as covariates in models comprising the 'group' variable. To avoid multicollinearity between WAZ and MUACZ scores, the score with a greater correlation with the outcome variable was selected. The interactions between baseline age and time, and baseline score and time were also included simultaneously in the expanded model.

The final models included three variables potentially capable of modifying the treatment effect on the primary and the secondary outcomes. Each of these variables (sex, baseline age and baseline developmental level, or baseline anthropometric z-scores) and their interactions with the duration of follow-up and with treatment were separately examined. A backward selection procedure was used to obtain a parsimonious model. Statistical significance was set at $p<0.05$.

For the intervention group, a GEE model was also employed to look into the effect of aspects related to the intervention on the outcomes. The frequency of daily home-based guided stimulation of the child, the social-emotional score of the child, whether the child had been sick, receiving 'RUTF', or getting a specially prepared diet during the follow-up period were entered simultaneously in the GEE model.

Finally, the developmental performances (FM, GM, LA, PS and SE) and two anthropometric indices (WAZ and MUACZ) of the SAM children in the control and intervention groups were compared to nearly age-matched healthy children using multiple regression (with a correction for age and gender) (a) before the start of the intervention in hospital, and (b) six or more months after discharge from hospital. Data analysis was conducted using Stata (Version 12, StataCorp, College Station, Texas)(StataCorp, 2011).

2.3.3.7. Ethics

The study was carried out in accordance with the Helsinki Declaration and international ethical guidelines for biomedical research involving human subjects. Ethical approval was obtained from the Research Ethics Review Board of Jimma University (RPGC/217/2010), Ethiopia, and Hasselt University (CME 2010/306), Belgium. Child caregivers signed informed consent to participate in the study. SAM children in hospital were provided all routine medical care, and the facilities at the playground were accessible to all, regardless of the treatment group they were assigned to. The trial was registered at the US National Institutes of Health (ClinicalTrials.gov) # NCT03036176.

2.3.4 Results

2.3.4.1. Baseline characteristics of the control and the intervention groups

In total, 339 SAM children (male =183; mean ±SD age=27.4±15.1mo, range=6.1—65.7mo) were enrolled in the study (control=170 and intervention=169) (Fig 2.3.1).

The composition of the control and intervention group was compared for baseline child, maternal, and family characteristics. The results are presented in Table 1. The two groups differ significantly in terms of living area, maternal occupation, child's baseline WAZ and MUACZ scores. More children from urban or semi-urban areas were assigned to the intervention (30.8% versus 15.9%, p=0.001). Significantly more mothers in the control group were housewives (90.4% versus 78.2%, p=0.002). In terms of the MUACZ and WAZ scores, the intervention children had better baseline scores than the control children (z-score = -3.1 versus -3.5, p=0.014; and -3.6 versus -3.9, p=0.048 respectively).

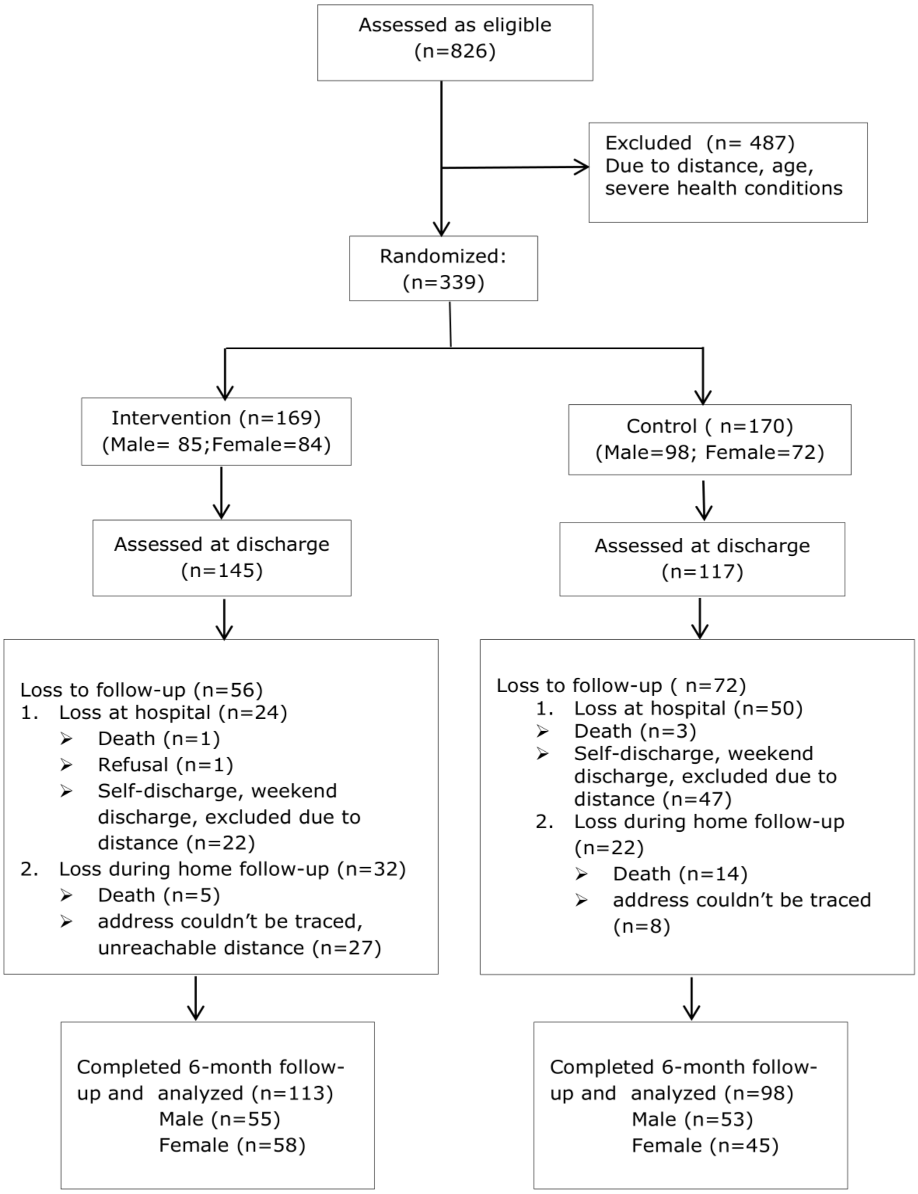

Figure 2.3.1. Flow chart of sample enrolled and finally analysed

No statistically significant differences were observed between control and intervention children at baseline on child age, sex, birth order, developmental performance, family size and income. The two groups were also similar in duration of stay in hospital (mean (SD)12.12 ±9.7, range 1-46 days for control group; 12.10±8.3, range 2-48 days for intervention group), nutritional status as measured by HAZ and WHZ or BAZ, and in maternal education. Most of the children (80%) in each group belonged to illiterate mothers; more than 70% of them lived in a family of 3 to 6 persons; more than half were born after a second child; more than 98% lived in a family with a monthly income of less than 1500 birr (about 72 USD at the time); more than 78% of the mothers were younger than 31 years of age.

2.3.4.2. Baseline characteristics related to loss to follow-up

Of the 339 children initially enrolled, only 211 children (98 control, 113 intervention) completed the study (Fig. 2.3.1). The rate of loss to follow-up did not differ significantly between the two groups (42.4% control versus 33.1% intervention, p=0.08). Reasons for loss (Fig. 2.3.1) include death of the

Table 1 Baseline characteristics (child, maternal and family characteristics) of SAM children by trial arm (N=339), displayed as n (%) or mean [95% CI].

	N (339)	Intervention	Control	p-value
Child characteristics				
Female (n, %)	339	84 (49.7)	72 (42.4)	0.175
Birth order (born after second child) (n,%)	337	90 (53.3)	97 (57.7)	0.589
Age, months	339	27.5 [25.3, 29.7]	27.3 [24.9, 29.7]	0.908
HAZ baseline score	337	-3.7 [-4.0, -3.5]	-3.8 [-4.1, -3.5]	0.558
MUACZ baseline score	332	-3.1 [-3.3, -2.9]	-3.5 [-3.8, -3.2]	0.014*
WAZ baseline score	338	-3.6 [-3.8, -3.4]	-3.9 [-4.1, -3.6]	0.048*
WHZ or BAZ baseline score	337	-2.3 [-2.5, -2.0]	-2.6 [-2.9, -2.3]	0.128
Fine motor baseline score	338	15.6 [14.9, 16.3]	15.3 [14.5, 16.1]	0.580
Gross motor baseline score	339	16.2 [15.5, 17.0]	16.3 [15.4, 17.1]	0.998
Language baseline score	339	16.6 [15.7, 17.6]	17.1 [16.0, 18.2]	0.546
Personal social baseline score	339	14.2 [13.3, 15.0]	14.0 [13.0,15.0]	0.773
Social-emotional baseline score	336	67.3 [62.5, 72.0]	66.8 [62.2, 71.4]	0.888
Maternal characteristics				
Age (≤30 yrs.) (n, %)	330	134 (81.2)	130 (78.8)	0.582
Education (illiterate) (n,%)	338	135 (79.9)	135(79.9)	0.100
Occupation (house wife) (n, %)	331	129 (78.2)	150 (90.4)	0.002*
Family characteristics				
Family size (2-6 persons) (n, %)	339	121 (71.6)	121 (71.2)	0.932
Socio-economic status (<2.4 USD/day) (n, %)	338	167(98.8)	166 (98.2)	0.652
Address (rural or small village) (n, %)	339	117 (69.2)	143 (84.1)	0.001*

T-test used for comparison on continuous score summarized by Mean (SD); Chi-square test for comparison of binary scores summarized by n (%); * p<0.05

children (n=23), self-discharge, weekend discharge and/or failure to trace a child's address or/and failure by nurses to travel long distances for home follow-up (intervention, n=47; control, n=55), and a refusal for follow-up by one intervention child. The baseline characteristics of children completing the study and those lost to follow-up were compared on socio-demographic profiles, and main study outcomes at baseline (child development and growth) (Table 2).

At baseline, children who completed the study and those lost to follow-up did not differ significantly except on the ASQ-SE score and location of residential area (urban / rural or small village).

Table 2 Baseline characteristics (child, maternal and family characteristics) for the SAM children completing the study and the SAM children lost to follow-up displayed is n (%) or mean [95% CI].

	N (339)	Completers (n=211)	Lost to follow-up (n=128)	p-value
Child and demographic characteristics				
Female (n, %)	339	105 (49.8)	51 (39.8)	0.076
Birth order (born after 2nd child) (n,%)	337	113 (53.8)	74 (58.3)	0.258
Age, months	339	26.7 [24.7, 28.7]	28.5 [25.7, 31.3]	0.303
Linear growth and nutritional status				
HAZ baseline score	337	-3.7 [-4.0, -3.5]	-3.8 [-4.2, -3.5]	0.641
MUACZ baseline score	332	-3.2 [-3.4, -3]	-3.5 [-3.8, -3.2]	0.110
WAZ baseline score	338	-3.7 [-3.9, -3.5]	-3.8 [-4.1, -3.6]	0.420
WHZ or BAZ baseline score	337	-2.4 [-2.7, -2.2]	-2.5 [-2.8, -2.1]	0.893
Developmental status				
Fine motor baseline score	338	15.6 [14.9, 16.2]	15.3 [14.4, 16.3]	0.634
Gross motor baseline score	339	16.3 [15.6, 17]	16.2 [15.3, 17.1]	0.906
Language baseline score	339	16.4 [15.5, 17.3]	17.6 [16.3, 19]	0.135
Personal social baseline score	339	14 [13.1, 14.8]	14.3 [13.2, 15.4]	0.644
Social-emotional baseline score	336	64 [59.8, 68.1]	72.1 [66.7, 77.5]	0.009*
Maternal characteristics				
Age (≤ 30 years) (n, %)	330	166 (79.4)	98 (81)	0.732
Education (Illiterate) (n,%)	338	203 (96.6)	123 (96.1)	0.782
Occupation (house maid) (n, %)	331	175 (84.5)	104 (83.9)	0.871
Family characteristics				
Family size (2-6 persons) (n, %)	339	158 (74.9)	84 (65.6)	0.068
Socio-economic status (< 2.4 USD per day [a]) (n, %)	338	207 (98.6)	126 (98.4)	0.921
Address (rural or small village) (n, %)	339	154 (73)	106 (82.8)	0.038*

[a] Is about 1500 Ethiopian birr per month; * p<0.05

On average, children completing the study had fewer social-emotional problems (as indicated by the lower scores) than children lost to follow-up (64 versus 72.1, p=0.009), and those living in small villages or rural areas were more likely to drop out (83% versus 73%, p=0.038). The percentage of males and females among study completers is nearly the same (50%). However, the percentage of lost to follow-up is higher among males: 32.7% of the girls and 42.1% of the boys were lost to follow-up.

2.3.4.3. Developmental and nutritional outcomes of the study completers

Both the control and the intervention groups that completed the study improved during the follow-up period. Table 3 summarizes the mean scores of the two groups at baseline, discharge and end-line measurements.

Table 3 The baseline [a], midline [b], and end-line [c] mean [SD], p-value of the mean difference in developmental performance, linear growth and nutritional status of the control and the intervention SAM children who completed the study

	Developmental outcomes									
Time	Fine motor		Gross motor		Language		Personal-social		Social-emotional	
Group	Cont.	Int.	Cont	Int.	Cont.	Int.	Cont.	Int.	Cont.	Int.
Baseline	15.3 [5.1]	15.8 [4.4]	16.1 [5.5]	16.5 [4.7]	16.2 [6.9]	16.6 [6.1]	13.5 [6.6]	14.4 [5.3]	63.9 [31.5]	64.1 [30]
P-value [d]	p=0.200		p=0.301		p=0.360		p=0.141		p=0.483	
Discharge	15.7 [4.6]	16.8 [4.3]	16.1 [5.6]	17.7 [4.9]	16.4 [6.9]	17.3 [6.6]	13.8 [6.1]	15 [5.6]	48.6 [27.3]	50.1 [29.2]
P-value [d]	p=0.046		p=0.020		p=0.177		p=0.082		p=0.361	
End-line	17.9 [4.1]	19.3 [3.3]	20.4 [5.8]	21.1 [5.3]	20.1 [7.4]	21.0 [6.9]	16.9 [5.1]	17.7 [4.4]	50.1 [28.9]	48.3 [22.8]
P-value [d]	p=0.003		p=0.210		p=0.186		p=0.110		p=0.695	
Overall mean	16.3 [4.8]	17.3 [4.3]	17.6 [6.0]	18.4 [5.3]	17.7 [7.3]	18.3 [6.8]	14.8 [6.1]	15.7 [5.3]	54.5 [30.1]	54.2 [28.3]

	Linear growth and nutritional outcomes							
	HAZ		MUACZ		WAZ		WHZ or BAZ	
Group	Cont.	Int.	Cont.	Int.	Cont.	Int.	Cont.	Int.
Baseline	-3.8 [1.9]	-3.7 [1.8]	-3.4 [1.8]	-3.0 [1.7]	-3.9 [1.5]	-3.5 [1.4]	-2.6 [1.8]	-2.3 [1.7]
P-value [d]	0.202		0.042		0.054		0.069	
Discharge	-3.9 [1.9]	-3.7 [1.6]	-3.2 [1.6]	-2.7 [1.4]	-3.8 [1.4]	-3.3 [1.3]	-2.0 [1.7]	-1.8 [1.4]
P-value [d]	0.267		0.009		0.123		0.222	
End-line	-3.7 [1.6]	-3.5 [1.4]	-1.2 [1.4]	-1.0 [1.4]	-2.5 [1.5]	-2.6 [2.2]	-0.5 [1.3]	-0.6 [1.4]
P-value [d]	0.199		0.154		0.596		0.644	
Overall mean	-3.8 [1.8]	-3.6 [1.6]	-2.6 [1.9]	-2.3 [1.7]	-3.3 [1.6]	-3.2 [1.7]	-1.7 [1.8]	-1.6 [1.7]

[a] before start of the psychomotor/psychosocial intervention; [b] at discharge from hospital; [c] after six months of home follow-up; [d] p-value for a difference between the control and the intervention means; BAZ=body-mass-index-for-age-z score, Con, control; Int= intervention; HAZ=height or length-for-age-z score; MUACZ=mid-upper-arm-circumference-for-age z score; WAZ=weight-for-age -z score; WHZ =Weight-for-height/length-z score; SD, standard deviation; T-test used to determine p-value for mean difference.

Age determines the scores on the four development outcomes assessed with Denver II-Jimma. However, age-matching was not possible at randomization. Therefore, we examined whether or not there was a significant association between the group to which the children were allocated and their age distribution across six age categories (< 6 mo., 12-24 mo., 24-36 mo. 36-48 mo., 48-60 mo. and 60-65 mo.). We found no statistically significant association except for age categories >=48 mo., where more control than intervention children (20 vs 12., p=0.001) were followed up (Table 4).

Table 4 Age wise comparison [a] of the control (n=98) and the intervention (n=113) SAM children who completed the study

	Number of SAM children allocated to control and intervention by age category												
	< 12 mo.		12-24 mo.		24-36 mo.		36-48 mo.		48-60 mo.		60-65 mo.		
Follow-up phase	Con	Int	Con	Int	Con	Int	Con	Int	Con	Int	Con	Int	$chi2$
Baseline	21	15	34	39	16	29	14	18	8	11	5	1	7.7 p=0.183
Discharge	19	14	33	38	16	39	10	20	6	11	14	1	19.97[±] p=0.001
End-line	-	-	39	29	24	38	14	27	14	13	7	6	7.84 p=0.096

[a] Comparison using Chi-square test of association
[±] When age categories >= 48 mo. are excluded there is no significant association ($Chi2$ = 5.3, p=0.153)
Con, control; Int, intervention

2.3.4.4. Adherence to study protocol for the intervention group

Of the 113 intervention children completing the follow-up, five did not attend any of the planned hospital-based developmental stimulation sessions. Seventy (61.9%) children had less than the initially planned minimum individual playroom sessions because they left the hospital; either their caregivers wanted to leave for home, or physicians decided a discharge to avail treatment space for patients with more severe cases. Six children (5.3%) had less than three of the planned home visits.

2.3.4.5. Effect of psychomotor-psychosocial stimulation on development, linear growth and nutritional status of SAM children

The results from the primary GEE model (without adjusting for baseline covariates) to estimate the effects of the intervention during (a) the hospital follow-up period, (b) the home-based follow-up period after discharge from hospital, and (c) during the whole follow-up period on primary and secondary outcomes (reflected in HAZ, MUACZ, WAZ and WHZ or BAZ scores) have been summarized (Table 5). There were some improvements over time for all outcomes (development, linear growth and nutritional status), but the improvement for the control and for the intervention groups differed significantly only in gross motor score during hospital follow-up and in fine motor score during the home follow-up period. The improvement in gross motor functions during the hospital follow-up period was higher in the intervention than the control group on average by 0.88 points ($p<0.001$, effect size=0.26 SD).

The improvement in fine motor functions was higher for the intervention than the control group during the home based follow-up period on average by 0.85 points ($p=0.001$, effect size= 0.15 SD), and each day during the whole follow-up period by 0.13 points ($p=0.033$, effect size= 0.22 SD). The effect sizes are, however, small. On the other hand, no significant differences were observed between the two groups in linear growth (HAZ) and nutritional outcomes (MUACZ, WAZ and WHZ or BAZ) (Table 5, Fig. 2.3.2).

Analysis was also conducted by adjusting for variables that were significantly different between the two groups at baseline. The analysis aimed at examining the overall effect of the intervention (hospital and home based follow-up periods combined) by using time in the GEE model as a continuous variable. The conclusion is similar to the results obtained from the basic GEE model summarized in Table 5. To examine if there was a significant influence from the high loss-to-follow-up, the findings from three methods (complete case analysis, direct likelihood and multiple imputation) were compared using linear mixed model. Again, the same conclusion has been reached.

Table 5 Average increase [a] [95% CI] in developmental performance, linear growth and nutritional status from baseline to discharge, and from discharge to end-line and baseline to end-line, and effect size [b] of the mean differences.

Developmental outcomes

	Increase from baseline to discharge [b]			Increase from discharge to end-line [b]			Increase from baseline to end-line [c]		
Outcomes	Control group	Intervention effect	Effect size	Control group	Intervention effect	Effect size	Control group	Intervention effect	Effect size
Fine Motor	0.73‡ [0.28, 1.16] p<0.001	0.31‡ [-0.29, 0.94] p= 0.299	0.07	1.73‡ [1.1, 2.4] p<0.001	0.85‡ [0.1, 1.6] p= 0.023	0.15†	2.50† [1.9, 3.1] p= 0.001 0.38¥ [0.28, 0.47] p<0.001	1.09† [0.5, 1.7] p= 0.001 0.13¥ [0.01, 0.24] p= 0.033	0.22
Gross Motor	0.36‡ [0.01, 0.7] p= 0.044 0.40† [0.07, 0.74] p= 0.019	0.98‡ [0.5, 1.5] p= 0.001 0.88† [0.40, 1.37]p<0.001	0.26	3.9‡ [3.3, 4.5] p<0.001	-0.6‡ [-1.5, 0.3] p=0.222	-0.20	4.3‡ [3.6, 4.9] p<0.001 0.63¥ [0.54, 0.73] p<0.001	0.4‡ [-0.50, 1.3] p= 0.376 -0.004¥ [-0.14, 0.13] p= 0.948	0.06
Language	0.5 [0.1, 1.0] p= 0.022	0.01 [-0.7, 0.7] p= 0.966	0.003	3.3‡ [2.5, 4.0] p<0.001	0.5‡ [-0.5, 1.5] p=0.326	0.07	3.8‡ [3.0, 4.5] p<0.001 0.55¥ [0.44, 66] p<0.001	0.5‡ [-0.5, 1.5] p=0.329 0.07¥ [-0.07, 0.21] p=0.341	0.07
Personal-social	0.7‡ [0.3, 1.0] p= 0.001	-0.06‡ [-0.6, 0.4] p=0.812	-0.02	2.6‡ [2.0, 3.2] p<0.001	0.12‡ [-0.7, 0.9] p=0.762	0.03	3.2 ‡ [2.6, 3.8] p<0.001 0.46¥ [0.37, 0.55] p<0.001	0.06‡ [-0.7, 0.8] p=0.865 0.01¥ [-0.11, 0.13] p=0.887	0.011
Social-Emotional	-12.8‡ [-17.0, -8.5] p= 0.001	1.7‡ [-4.3, 7.7] p= 0.583	0.04	-1.8‡ [-7.6, 3.9] p= 0.256	-4.3‡ [-12.4, 3.8] p= 0.295	-0.09	-14.6‡ [-20, -9.0] p<0.001 1.78¥ [-2.63, -0.94] p<0.001	-2.64‡ [-9.2, 3.9] p= 0.426 -0.36¥ [-1.50, 0.78] p= 0.541	-0.05

Linear growth and nutritional outcomes

	Increase from baseline to discharge [b]			Increase from discharge to end-line [b]			Increase from baseline to end-line [c]		
	Control group	Intervention effect	Effect size	Control group	Intervention effect	Effect size	Control group	Intervention effect	Effect size
HAZ	-0.05 ‡ [-0.2, 0.1] p= 0.419	-0.05‡ [-0.1, 0.1] p= 0.633	-0.03	0.2‡ [0.01,0.4] p=0.039	0.03‡ [-0.2, 0.3] p=0.790	0.03	0.2 ‡ [-0.1,0.4] p=0.138 0.03¥ [-0.01, 0.07 p=0.104	-0.004‡ [-0.3, 0.3] p=0.978 -0.01¥ [-0.05, 0.04] p=0.753	-0.002
MUACZ	0.3‡ [0.1, 0.4] p= 0.002 0.34† [0.24, 0.44] p<0.001	0.2‡ [-0.04, 0.35] P=0.123 0.15‡ [-0.04, 0.35] p=0.123	0.12	1.9‡ [1.6, 2.2] p<0.001	-0.2‡ [-0.5,0.2] p=0.430	<0.00 01	2.1‡ [1.8, 2.4] p<0.001 0.34¥ [0.29, 0.39] p<0.001	0.002‡ [-0.4, 0.4] p=0.999 -0.02¥ [-0.09, 0.05] p=0.596	<0.0001
WAZ	0.2‡ [0.03, 0.30] p= 0.022	0.1‡ [-0.1, 0.3] p= 0.260	0.08	1.1‡ [0.9, 1.3] p<0.001	-0.3‡ [-0.7,0.1] p=0.155	-0.20	1.3‡ [1.0, 1.5] p= 0.001 1.30.19¥ [0.15, 0.23] p<0.001	-0.2‡ [-0.7, 0.2] p=0.372 -0.06¥ [-0.13, 0.01] p=0.112	-0.02
WHZ or BAZ	0.5‡ [0.2, 0.8] p<0.001	0.04‡ [-0.2, 0.3] p= 0.791	0.02	1.5‡ [1.1, 1.8] p<0.001	-0.2‡ [-0.6, 0.2] p= 0.321	-0.04	2.0‡ [1.7, 2.3] p<0.001 0.29¥ [0.24, 0.34] p<0.001	-0.2‡ [-0.5, 0.2] p=0.352 -0.06¥ [-0.123, 001] p=0.054	-0.06

[a] The increase for the control group during the follow-up time and the intervention effect (additional increase for the intervention group). When there is no intervention effect, the average increase of the control group and intervention group are equal.
[b] A GEE model using time as a factor variable. [c] A GEE model using 'time' both as factor variable (parameters marked by "‡, †", and as a continuous variable (parameters marked by "¥". As a factor variable, 'time' indicates the follow-up phases (hospital-based, home-based or a combination of both). As a continuous variable, time indicates a mean change in the outcome variable when the duration of follow-up increases by one day).
‡ Obtained from a full model comprising time as factor variables (y=Time2 + Time3+ Time2*Treatment +Time3*Treatment, where Time1=0)
† Obtained from a reduced model comprising time as factor variables.
¥ Obtained from a full model comprising time as a continuous variable (y=Time + Treatment+ Time*Treatment)
In full model, parameter estimates are based on all significant and non-significant terms.
In reduced model, parameter estimates are based on a parsimonious model that includes statistically significant terms and only essential non-significant model terms. BAZ, body-mass-index-for-age z score; GEE, Generalized Estimating Equations; HAZ, height/length-for-age z score; MUACZ, mid-upper-arm-circumference z score; WAZ, weight-for-age z score; WHZ, weight-for-height/length z score.

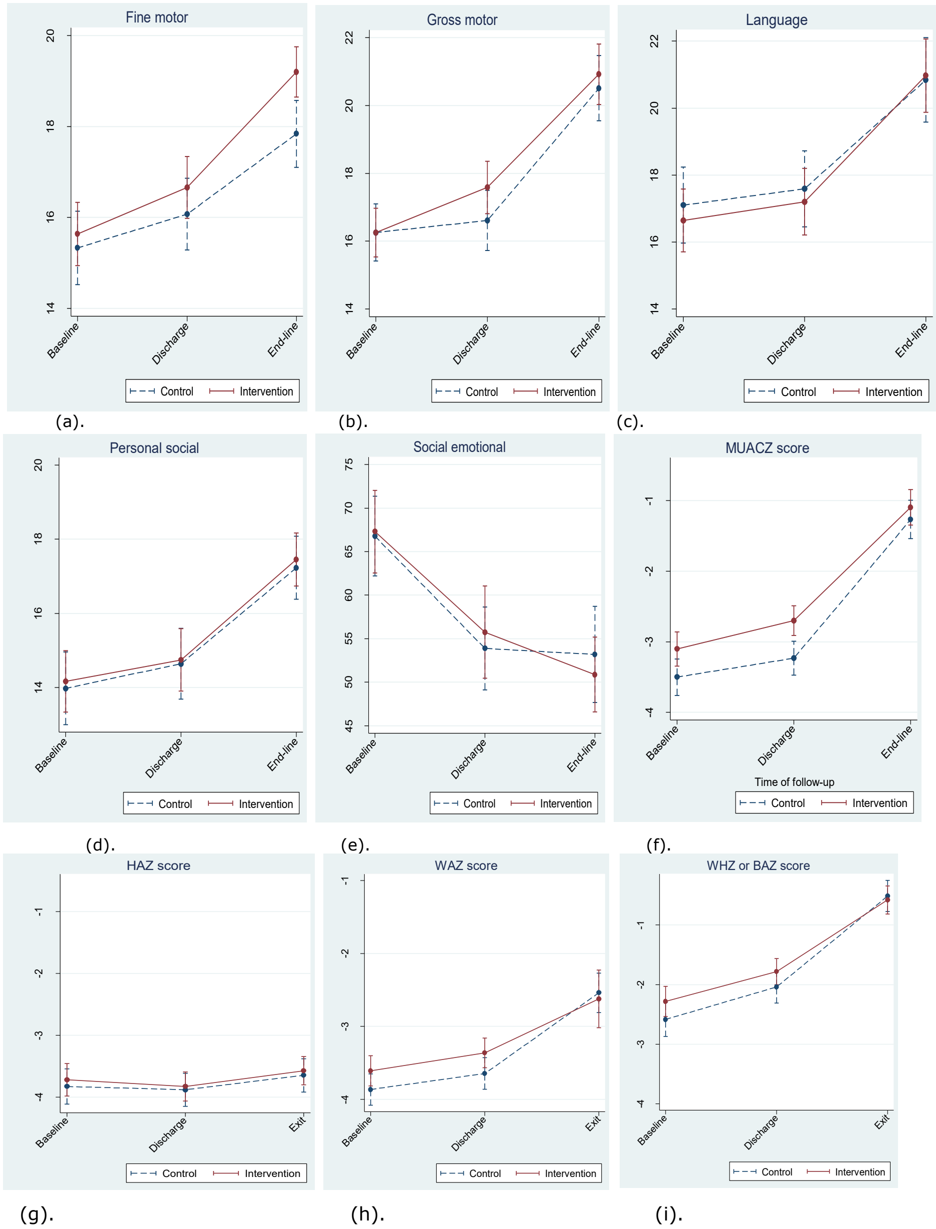

Figure 2.3.2. Developmental, linear growth and nutritional outcomes among the control and intervention SAM children during follow-up measurements

Figures were based on the basic GEE model comprising treatment, time (as indicator variable) and interaction between time and treatment**.**

2.3.4.6. Moderation effects of baseline scores on treatment outcomes

The relationship of the treatment with child's sex and baseline characteristics (age, developmental level, linear growth and nutritional status) during the whole follow-up period (hospital based and home-based follow-up periods combined) was assessed after adjusting for outcomes that were different between the control and intervention groups at baseline (maternal occupation, residential address, MUACZ and WAZ scores). A three-way interaction (treatment*follow-up*baseline characteristics/ sex) was examined separately for each outcome. The results are summarized in Table 6.

The treatment bears no relationship to the child's sex, baseline age and baseline developmental scores, linear growth, and nutritional status measured on MUACZ and WAZ scores. However, it is related to baseline WHZ or BAZ score: for a similar length of follow-up, the intervention children with better baseline WHZ or BAZ score benefitted more from the intervention ($\beta = 0.02$, $p=0.012$).

Table 6 Regression coefficients [95% CI] from the GEE models [a] with a continuous time scale (days in the study) depicting average change in developmental, growth and nutritional status during follow-up of the intervention

Explanatory variables		*Developmental outcomes* FM β (95%CI)	GM β (95%CI)	LA β (95%CI)	PS β (95%CI)	SE β (95%CI)
Group [b]		0.099 [é] [-0.18, 0.38] p=484	0.37 [é] [0.09, 0.65] p=0.010	-0.17 [æ] [-0.55, 0.21] p=0.377	0.11 [æ] [-0.39, 0.16] p=0.419	-0.22 [æ] [-3.55, 3,11] p=0.898
Time [c]	Linear term	1.10 [é] [0.91, 1.21] p<0.001	1.10 [é] [0.93, 1.24] p<0.001	0.81 [é] [0.68, 00.95] p<0.001	1.46 [é] [1.12, 1.80] p<0.001	-4.30 [æ] [-10.11, 1.57] p=0.151
	Quadratic term	-0.05 [æ] [-0.13, 0.02] p=0.151	0.04 [æ] [-0.05, 0.12] p=0.330	-0.03 [æ] [-0.13, 0.06] p=0.480	-0.06 [æ] [-0.10, -0.01] p=0.019	0.39 [é] [0.24, 0.54] p<0.001
Baseline data	MUACZ	0.15 [é] [0.07, 0.24] p<0.001	0.07 [æ] [-0.02, 0.16] p=0.127	-	0.13 [é] [0.06, 0.20] p<0.001	-0.45 [æ] [-1.30, 0.41] p=0.310
	WAZ	-	-	0.20 [é] [0.09, 0.31] p<0.001	-	-
	Development	0.76 [é] [0.71, 0.81] p<0.001	0.93 [é] [0.88, 0.98] p<0.001	0.81 [é] [0.76,0.86] p<0.001	0.87 [é] [0.83, 0.92] p<0.001	0.86 [é] [0. 81, 0. 91] p<0.001
	Age	0.06 [é] [0.04, 0.08] p<0.001	0.03 [é] [0.01, 0.04] p<0.001	0.08 [é] [0.05, 0.10] p<0.001	0.04 [é] [0.02, 0.06] p<0.001	0.13 [é] [0.04, 0.23] p=0.008
Time [c] *Baseline development		-0.06 [é] [-0.07, -0.04] p<0.001	-0.06 [é] [-0.07, -0.04] p<0.001	-0.06 [é] [-0.08, -0.05] p<0.001	-0.07 [é] [-0.08, -0.06] p<0.001	-0.08 [é] [-0.09, -0.06] p<0.001
Time [c] *Baseline Age		0.01 [é] [0.001, 0.012] p=0.018	0.02 [é] [0.01, 0.022] p<0.001	0.03 [é] [0.02, 0.04] p<0.001	0.014 [é] [0.001, 0.02] p=0.001	0.04 [0.01, 0.06] p=0.010
Group*Time [c] (Linear)		0.15 [æ] [0.07, 0.22] p<0.001	0.41 [æ] [-0.44, 1.27] p=0.344	0.02 [æ] [-0.92, 0. 96] p=0.971	-0.06 [æ] [-0.72, 0.59] p=0.850	1.63 [æ] [-6.73, 9,98] p=0.703
Group*Sex [f] *Time (Linear)	FCon [g]	-0.02 [æ] [-0.13, 0.08] p=0.657	-0.07 [æ] [-0.20, -0.06] p=0.302	-0.08 [æ] [-0.21, 0.05] p=0.240	-0.004 [æ] [-0.1, 0.09] p=0.940	0.29 [æ] [-0.92, 0.50] p=0.638
	FIn [h]	0.01 [æ] [-0.09, 0.11] p=0.827	-0.02 [æ] [-0.14, -1.00] p=0.742	0.04 [æ] [-0.08, 0.17] p=0.525	0.08 [æ] [-0.17, 0.01] p=0.086	0.47 [æ] [-1.60, 0.67] p=0.421
Group*Baseline development* Time (Linear)		0.02 [æ] [-0.01, 0.04] p=0.206	-0.02 [æ] [-0.05, 0.003] p=0.086	0.004 [æ] [-0.02, 0.03] p=0.765	-0.02 [æ] [-0.04, 0.004] p=0.102	-0.02 [æ] [-0.04, 0.01] p=0.236
Group*Baseline Age*Time (Linear)		-0.005[æ] [-0.01, 0.004] p=0.253	0.01 [æ] [-0.004, 0.01] p=0.278	0.001 [æ] [-0.01, 0.01] p=0.889	0.01 [æ] [-0.001, 0.02] p=0.072	-0.01 [æ] [-0.07, 0.06] p=0.861
		Linear growth [d] and nutritional [e] outcomes				

Explanatory variables		HAZ	MUACZ	WAZ	WHZ/BAZ
Group [b]		-0.26 [æ] [-0.57, 0.06] p=0.101 p=0.113	0.07 [æ] [-0.12, 0.26] p=0.461	-0.215 [æ] [-0.05, 0.47] p=0.119	0.22 [æ] [-0.13, 0.58] p=0.214
Time [c]	Linear term	-0.09 [é] [-0.11, -0.07] p<0.001	0.19 [æ] [-0.05, 0.44] p=0.122	0.28 [æ] [0.04, 0.53] p=0.025	0.33 [é] [0.07, 0.59] p=0.008
	Quadratic term	0.004 [æ] [-0.03, 0.02] p=0.765	-0.02 [æ] [-0.05, 0.02] p=0.360	-0.03 [æ] [-0.06, 0.001] p=0.061	-0.04 [é] [-0.08, -0.001] p=0.045
Baseline data	HAZ	0.85 [é] [0.81, 0.88] p<0.001	0.004 [æ] [-0.02, 0.03] p=0.727	0.07 [é] [0.01, 0.13] p=0.024	0.02 [æ] [-0.10, 0.14] p=0.733
	MUACZ	-	0.92 [é] [0.88, 0.96] p<0.001	-	-
	WAZ	0.13 [é] [0.08, 0.17] p<0.001	0.08 [é] [0.04, 0.13] p=0.001	0.85 [é] [0.79, 0.90] p<0.001	0.004 [æ] [-0.22, 0.21] p=0.972
	WHZ or BAZ	-	-	-	0.82 [æ] [0.75, 0.88] p<0.001
	Age	-0.005 [æ] [-0.01, -0.001] p=0.011	-0.001 [æ] [-0.003, 0.003] p=0.949	0.002 [æ] [-0.001, 0.004] p=0.219	0.01 [é] [0.001, 0.010] p=0.012
Time [c]*Baseline HAZ		-0.033 [é][-0.038,-0.028]p<0.001	0.01 [æ] [-0.01, 0.04]p=0.202	0.01 [æ] [-0.01, 0.04] p=0.265	0.005 [æ] [-0.03, 0.04] p=0.782
Time [c]*Baseline MUACZ		-	-0.09 [é] [-0.10, -0.08] p<0.001	-	-
Time [c]*Baseline WAZ		0.01 [æ] [-0.04, 0.05] p=0.800	-0.01 [æ] [-0.04, 0.02] p=0.556	-0.042 [é] [-0.05,-0.036] p<0.001	0.02[æ] [-0.04, -0.07] p=0.510
Time [c]*Baseline WHZ or BAZ		-	-	-	-0.09 [é] [-0.11, -0.07] p<0.001
Time [c]*Baseline Age		0.001 [æ] [-0.002, 0.004] p=0.547	-0.001 [æ] [-0.004, 0.002] p=0.589	-0.001 [æ] [-0.003, 0.001] p=0.328	0.0002 [æ] [-0.003, 0.002] p=0.824
Group*Time [c]*baseline HAZ		0.02 [æ] [-0.01, 0.05] p=0.260	-	-	-
Group*Time*baseline MUACZ		-	-0.01[æ] [-0.005, 0.05] p=0.879	-	-
Group*Time*baseline WAZ		-	-	-0.001[æ] [-0.05, 0.05] p=0.970	-
Group*Time*baseline WHZ or BAZ		-	-	-	0.02 [é] [0.01, 0.04] p=0.012
Group*Time*sex	FCon [g]	-0,02 [æ] [-0.08, 0.05] p=0.594	-0.04 [æ] [-0.12, 0.05] p=0.408	-0.05 [æ] [-0.12, 0.02] p=0.136	-0.03 [æ] [-0.12, 0.06] p=0.514
	FIn [h]	-0.004 [æ] [-0.05, 0.04]p=0.868	-0.06 [æ] [-0.12, 0.01] p=0.102	-0.05 [æ] [-0.17, 0.06] p=0.389	-0.01 [æ] [-0.08, 0.06] p=0.819

Only significant terms (at $p < 0.05$) were kept in the models.
[a] Intervention effect controlling for baseline score, baseline characteristics, and interactions with time.
[b] Refers to the intervention group (treatment)
[c] 'Time' refers to number of days in the study (duration of follow-up); [d] 'growth' refers to baseline linear growth expressed in HAZ score
[e] 'nutritional' refers to baseline nutritional status expressed in MUACZ score and WAZ score.
[f] sex; the reference is female; [g] FCon, Female control; [h] FIn, Female intervention.
[æ] Parameter estimates obtained from a full model by simultaneously including all potential explanatory variables
[é] Parameter estimates obtained from a reduced model with statistically significant explanatory variables along with only essential non-significant model terms; BAZ, body-mass-index-for-age z score; FM, fine motor; GEE, Generalized Estimating Equations; GM, gross motor; HAZ, height/length-for-age z score; LA, language; MUACZ, mid-upper-arm circumference -for-age z score; PS, personal-social; SE, Social-Emotional; WAZ, weight-for-age z score; WHZ, weight-for-height/length z score.

2.3.4.7. Factors affecting performance of the intervention children

Some factors which were thought to affect the performance of the intervention SAM children were examined. After adjusting for some child conditions (health status, baseline social-emotional scores), a significant association was observed between access to RUTF and performance on gross motor and language (Table 7). Yet the result has to be interpreted carefully since the final home visit interviews to caregivers showed that 73.4% of the intervened SAM children did not receive RUTF at all. Of those who had access to RUTF, those who were reported to have been receiving RUTF sometimes from nearby health centres scored significantly higher in language (β=1.41, p=0.032, effect size=0.21 SD) than the children who rarely or never received RUTF at all. On the other hand, those reported to have always been receiving/collecting RUTF from nearby health centre scored significantly lower in GM (β=-0.93, p=0.031). This does not mean consuming RUTF reduces gross motor function. Rather, it might refer to the children who were in a critical need for RUTF because their condition did not improve, and/or caregivers are so poor that they collect RUTF more often than others. Compared to those who were reported to be sick, SAM children who were not sick during the home follow-up scored significantly higher on personal social (β = 0.51, p=0.047) but lower on language (β = -1.11, p=0.024). A lower SE score (i.e., better behaviour) predicts better outcomes on FM. With an increase in SE score (which marks more problem behaviours), performance on FM decreased significantly (β= -0.02, p=0.016).

Table 7 Regression coefficients [95% CI] from the GEE models [a] examining some factors modifying the effect of the intervention on developmental outcomes

Explanatory variables		Developmental outcomes FM β (95%CI)	GM β (95%CI)	LA β (95%CI)	PS B (95%CI)	SE β (95%CI)
Duration of follow up (days in study)		0.45 [0.39, 0.52] p<0.001	0.57 [0.47, 0.68] p<0.001	0.62 [0.52, 0.72] p<0.001	0.49 [0.41, 0.56] p<0.001	-1.7 [-2.58, -0.75] p<0.001
Number of stimulation sessions in hospital [b]		0.07[-0.07, .22] p= 0.329	0.07 [-0.1,0.2] p= 0.415	0.08 [-0.3, 0.5] p= 0.691	0.06 [-0.1, 0.2] p= 0.530	0.97 [0.07, 0.19] p= 0.034
Two or more [c] stimulation sessions at home		-0.2 [-0.7, 0.3] p= 0.432	-0.001[-0.6, 0.6] p= 0.998	-0.7 [-1.9, 0.5] p= 0.249	-0.2 [-0.7, 0.4] p= 0.571	-3.3 [-9.6, 2.95] p= 0.301
How often [d] the intervention SAM child received RUTF from a nearby health centre	Always	-0.5 [-1.1, 0.3] p= 0.234	-0.93 [-1.78, -0.09] p= 0.031	0.1 [-1.1, 1.4] p= 0.842	-0.1 [-0.7, 0.5] p= 0.714	-0.8 [-6.9, 5.2] p= 0.789
	Some-times	-0.2 [-1.1, 0.7] p= 0.727	-0.6 [-1.3, 0.1] p= 0.112	1.41 [0.12, 2.70] p= 0.032	-0.4 [-1.1, 0.3] p= 0.281	1.3 [-7.1, 9.6] p= 0.767
Whether or not the intervention SAM child was sick after discharge from hospital [e]		0.09 [-0.5, 0.7] p= 0.781	0.2 [-0.5, 0.9] p= 0.520	-1.11 [-2.10, -0.15] p= 0.024	0.51 [0.01, 1.01] p= 0.047	-3.3 [-9.6, 2.9] p= 0.297
Whether or not the intervention SAM child was getting home-prepared special food during the home follow-up		-0.2 [-1.0, 0.5] p= 0.552	0.6 [-0.05, 1.2] p= 0.071	-0.5 [-1.6, 0.6] p= 0.414	-0.1[[-0.5, 0.4] p= 0.789	-3.4 [-9.2, 2.4] p= 0.255
Social-emotional scores of the child during the follow-up		-0.02* [-0.03, -0.003] p= 0.016	-0.01 [-0.03, 0.001] p= 0.068	-0.01 [-0.03, 0.02] p= 0.543	-0.003 [-0.01, 0.01] p= 0.544	-

[a] All the covariates were entered simultaneously into the GEE model for each developmental domain.
[b] 'Stimulation sessions' refers to total number of play sessions in the play room and playground the intervention SAM child received before discharge from hospital; [c] reference is only 'once a day'; [d] reference is 'rarely or not at all'
[e] The reference is "being sick"
FM, fine motor; GEE, Generalized Estimating Equations; GM, gross motor; LA, language; PS, personal-social; SE, Social-Emotional.

Increasing the duration of follow-up of the intervention significantly predicts improvement in all the developmental outcomes (Table 7). The duration of follow-up in hospital and the number of play sessions the intervention children attended there varied accordingly. When entered alone in the model (Table 8), the number of play sessions that the SAM children received in hospital was associated significantly with all developmental outcomes, except with social-emotional scores. When entered simultaneously with covariates other than length of stay in hospital, more play sessions were associated with a higher social-emotional score (mean = 0.97, 95%CI [0.08, 0.19]) (Table 7). However, adjusting for the length of stay in hospital makes the association with SE-score non-significant. When entered separately in the model, the duration of follow-up predicted all outcomes. Longer follow-up predicted better developmental, linear growth, and nutritional outcomes (Table 8).

Table 8 Regression coefficients [95% CI] from the GEE models [a] separately examining some selected factors modifying the effect of the intervention on development, linear growth and nutritional outcomes

	Selected explanatory variables		
Outcomes	Duration of follow up (days in study)	Number of stimulation sessions in hospital [b]	Whether or not the intervention SAM child was sick after discharge from hospital
FM	0.48 [0.41, 0.54] p<0.001	0.14 [0.01, 0.27] p= 0.040	-0.4 [-1.2, 0.4] p= 0.335 -0.4 [-1.2, 0.4] p= 0.289
GM	0.62 [0.52, 0.71] p<0.001	0.18 [0.02, 0.33] p= 0.026	
LA	0.59 [0.49, 0.69] p<0.001	0.23 [0.03, 0.44] p= 0.024	-0.01 [-0.8, 0.7] p= 0.976
PS	0.47 [0.40, 0.54] p<0.001	0.17 [0.003, 0.33] p= 0.046	-0.3 [-1.0, 0.4] p= 0.417
SE	-1.9 [-2.6, -1.09] p<0.001	0.22 [-0.5, 1.0] p= 0.550	-4.3 [-11.0, 2.3] p=0.204
HAZ	0.03 [0.003, 0.05] p=0.027	-0.004 [-0.05, 0.04] p= 0.862	-0.2 [-0.4, -0.05] p= 0.010
MUACZ	0.32 [0.27, 0.36] p<0.001	-0.02 [-0.07, 0.02] p= 0.369	-0.3 [-0.5, 0.06] p= 0.128
WAZ	0.13 [0.07, 0.20] p<0.001	-0.004 [-0.04, 0.04] p= 0.836	-0.2 [-0.4, 0.06] p= 0.128
WHZ or BAZ	0.24 [0.20, 0.28] p<0.001	-0.01[-0.06, 0.03] p= 0.500	0.1 [-0.2, 0.4] p= 0.496

[a] All the covariates were entered separately into the GEE model for each outcome.
[b] 'Stimulation sessions' refers to total number of play sessions in play room and playground the intervention SAM child received before discharge from hospital; [c] reference is only 'once a day'
BAZ, body-mass-index-for-age-z score; FM, fine motor; GEE, Generalized Estimating Equations; GM, gross motor; HAZ, height/length-for-age-z score; LA, language; UACZ, mid-upper-arm-circumference-for-age z-score; PS, personal-social; SE, Social-Emotional; WAZ, weight-forage-z score; WHZ, weight-for-height/length-z-score;

Finally, a comparison with age-matched healthy children showed that both the control and the intervention SAM children could not catch up after more than six months of follow-up, except on social-emotional behaviour, in which both groups did not differ from the healthy ones (Table 9).

Table 9 Baseline and end-line developmental performance and WAZ scores of SAM children [a] followed up for six months after discharge from hospital compared with healthy children [b]

Developmental and nutritional outcomes a	Baseline: before start of intervention		End-line: more than six months after start of intervention	
	Control Vs Healthy	Intervention Vs Healthy	Control Vs Healthy	Intervention Vs Healthy
	Mean difference[c] (95% CI)	Mean difference [c] (95% CI)	Mean difference [d] (95% CI)	Mean difference [d] (95% CI)
Fine Motor [e]	-3.5*** (-3.9, -3)	-3.2*** (-3.7,-2.9)	-3*** (-3.4,-2.6)	-2*** (-2.4, -1.6)
Gross Motor [e]	-5.76*** (-6.3, -5.2)	-5.79*** (-6.3,-5.3)	-4*** (-4.7, -3.6)	-4*** (-4.5, -3.5)
Language [e]	-5.1*** (-5.7, -4.5)	-5.4*** (-6, -4.8)	-4.6*** (-5.3, -4)	-4.6*** (-5.3. -4)
Personal Social [e]	-2.9*** (-3.6, -2.3)	-2.4*** (-3, -1.8)	-1.9*** (-2.4, -1.5)	-1.5*** (-1.9, -1.1)
Social-Emotional [f]	18.3*** (13.1, 23.5)	17.9*** (13.1,22.8)	-0.7 (-4.53, 6)	-1.9 (-6.7, 3)
WAZ [f]	-3.6*** (-4.3, -2.9)	-3.3*** (-3.9,-2.6)	-2.4*** (-2.6, -2.1)	-2. 4*** (-2.7,-2.2)

[a] SAM control (n=98); intervention (n=113)
[b] Healthy (n=1528 for baseline, and n=1318 for end-line)
[c] ANCOVA controlling for age
[d] ANCOVA controlling for [e] age; [f] age and sex.
Mean difference significant at *p<0.05; **p<0.01; ***p<0.001
ANCOVA= analysis of covariance; SD, Standard deviation; SAM= Severe acute malnourished; SE= Social-Emotional; WAZ= weight-for-age z-score

2.3.5. Discussion

The study shows play-based psychomotor/psychosocial stimulation benefits the motor (fine and gross) development of SAM children of six months to six years of age. For the gross motor functions, the intervention effect was significant during the shorter hospital-based period (12.1 ±8.95, range 1-48 days), but the effect became insignificant later during the six months of home follow-up. For the fine motor functions, the intervention effect became significant during the home follow-up. The effect of the intervention across the whole follow-up period was examined using analysis that combined both the hospital- and home-based follow-up periods, and showed a significant improvement in only the fine motor functions. The effect of the intervention was similar for both the younger and the older children. A non-significant but positive trend of improvement was observed in the other developmental domains (GM, LA, PS and SE). The intervention did not improve linear growth and nutritional outcomes.

An interesting finding is the difference in response of the gross motor and the fine motor functions to the intervention in different settings. The treatment effect on the gross motor skills was attained only during the hospital-based follow-up. For the SAM children, the diet at the nutritional rehabilitation unit of the hospital is not only better in quality, quantity and diversity, but is also provided at appropriate times with strict supervision of professionals on a daily basis. Moreover, caregivers dedicate their time fully to the child and remain in close contact. This is not the case in a home setting, where diet is inadequate, less diversified, non-balanced and also not served in a timely manner, since caregivers have other family responsibilities. The improvement might have been enhanced by the combined and synergistic effect of the psychomotor stimulation and the dietary therapy. The stimulation may facilitate the gross motor functions to be reactivated as soon as the large muscles regain strength from dietary rehabilitation. The fact that this effect became non-significant during the home-based follow-up could be attributed to the lack of adequate essential nutrients in the diet at home. At home, the children lack the standard daily nutritional care provided at the NRU of the hospital. The inverse relationship between gross motor performance and more frequent collection of RUTF from nearby health centres seems to contradict this finding. However, collection does not ensure provision of the RUTF to the child. Usually, caregivers who have serious food shortages collect and share it among other children in the family (Eklund & Girma, October 2008; Yebyo, Kendall, Nigusse, & Lemma, 2013). Since such children do not get the required amount, the implication of frequent collection of RUTF has to be interpreted carefully. There were challenges related to the utilization of RUTF from nearby health centres. In some cases, there were shortages of RUTF, and in other cases the RUTF collected was shared among other children in the family. In some other cases, parents could not regularly collect the RUTF due to the lack of a health centre in the vicinity. An interview with 112, 105 and 109 caregivers during the first, second and third (final) home visit respectively showed that 42.9%, 54.3% and 73.4% of the intervened SAM children did not receive RUTF at all. If children were not able to obtain an adequate diet, they may not have been active enough to engage in intensive motor activities. Therefore, this might have also reduced the gross motor stimulation at home and thereby resulted in a lack of significant intervention effect.

On the other hand, the significant intervention effect observed on fine motor only at a later time (during the home follow-up) might be explained in two ways. Firstly, unlike the gross motor activities, which demand relatively more physical strength and energy, the fine motor activities might be less demanding and more feasible for SAM children to engage in and practice. Secondly, it might reflect fine motor's slower response to the intervention. Recovery in fine motor functions might require more than a mere recovery of muscles: more integration of the muscles and the brain functions through a gradual process of holistic recovery in both physical and emotional states.

Though non-significant, the positive trend of improvement observed in the other areas of development could be related to such a gradual recovery process. The duration of the intervention in the present study might have been too short to generate a significant effect, as indicated in an earlier study (Baitun Nahar, Hossain, Hamadani, Ahmed, Grantham-McGregor, & Persson, 2012). Moreover, the intervention was not intensive. A maximum of only three home visits over a period of six months is not sufficient to provide adequate stimulation to the child and equip the mostly illiterate caregivers with effective stimulation techniques. Studies have shown a marked improvement in performance as the frequency of home visit increases (Powell & Grantham-McGregor, 1989; Wallander et al., 2014). Interventions targeting high-risk children, such as those who are malnourished, might need more frequent home visits to be more beneficial (J. Gardner et al., 2003). None of the studies conducted so far on the stimulation of SAM children has used so few home visits as the present study. It is argued that the impact of short stimulation programs during malnutrition episodes is temporary, particularly in conditions of extreme poverty to which the children return (Sally Grantham-McGregor, 1995). A depriving home environment and poor nutrition remain detrimental to the outcomes of the intervention. This is the case with the present study. All families of the SAM children belong to low socio-economic groups and live in poor home environments, all of which could compromise the care and attention that the SAM child needs. In short, parents are challenged to provide the intervention with a required intensity and a required dietary provision. This might have reduced the magnitude of the effect that could have been obtained from the intervention. Though the effect of the intervention in the present study is small, attaining it in such a context with limited support and resources shows that it has the potential to bring a better effect.

There are inconsistent findings with regard to the effect of psychomotor/psychosocial stimulation on measures of nutritional outcomes and motor development of SAM children. A review of studies conducted on Jamaican children with severe acute malnutrition (Daniel et al., 2017) showed that psychosocial stimulation improved fine motor but not gross motor development, as tested on the Griffiths Mental Development Scales. Though the intervention group performed better on gross motor (locomotor subscale on Griffiths test) at two-year follow-up, they were similar to the non-intervened control at the four-year follow-up. The intervention group remained significantly ahead of the malnourished control group for fine motor skills (eye-hand coordination subscale on the Griffiths test) at three–, four–, and five–year follow–up times, and scored similarly to the non–malnourished children.

A time-lagged controlled study on SAM Bangladeshi children 6-24 months of age (B. Nahar et al., 2009) showed improvement in motor development and WAZ score. A community-based randomized trial conducted later in the same country on severely underweight hospitalized children aged 6–24 months (Baitun Nahar, Hossain, Hamadani, Ahmed, Grantham-McGregor, & Persson, 2012) showed that psychosocial stimulation that included play activities and parenting education, with and without food supplementation, improved children's mental development and weight-for-age Z-score, but had no effect on motor development and linear growth. Inconsistencies across studies on some outcomes could be related to differences in study design, duration of follow-up, the children’s age and nutritional status, maternal education, and support from the health system, poverty level, assessment tools used, and quality and intensity of home stimulation.

Though their findings are inconsistent, earlier studies have targeted children under 24 months of age, or investigated the long-term effects of interventions which started at an early age and then continued later for some years (Chang, Walker, Grantham-McGregor, & Powell, 2002; Sally Grantham-McGregor et al., 1994; Sally Grantham-McGregor et al., 1983; Sally Grantham-McGregor et al., 1987; Sally M Grantham-McGregor, Walker, Chang, & Powell, 1997b; Susan P Walker et al., 2005; Susan P Walker et al., 2006). In the present study, children six months to six years were included. It is assumed that young children are likely to have more opportunities for mother-child interactions, better stimulation, and breast-feeding, which could buffer them against extreme malnutrition. However, the present study, which addressed children of more heterogeneous ages, has shown that the treatment effect does not depend on age. It showed that both younger and older children responded similarly to the treatment, implying the potential benefits of psychosocial/psychomotor stimulation to both younger and older children under the age of six.

At baseline, SAM children showed marked problems in all domains of development. Gross motor was found to be the worst affected domain (Abessa, Bruckers, Kosteren, & Granitzer, 2017). After more than six months of follow-up, both the control and the intervention groups could not catch up with healthy children on nutritional and the four developmental outcomes (FM, GM, LA and PS). However, the social-emotional behaviour improved markedly and was similar to that of healthy children (Table 8). Studies have already shown that SAM children have behavioural abnormalities during the acute stage, which spontaneously improve during the course of recovery (Sally Grantham-McGregor, 1995). The improvement in the present study followed a non-linear trend. A rapid improvement during the first four months of follow-up seems to have slowed down afterwards. Compared to the control SAM and the age-matched healthy children, the intervention SAM children showed substantially lower social-emotional problems.

Nonetheless, the result of our study has to be interpreted with some constraints and limitations**.** First, it was not possible to implement the intervention as planned. During hospital follow-up, the majority of children did not receive adequate stimulation sessions. Neither did their caregivers undergo sufficient education and training. This was because the SAM children had to leave the hospital and follow the treatment as out-patients in line with a protocol for the management of SAM children. The situation of some families also influenced the home-based stimulation. After home visits, supervisors and intervention workers often reported the presence of low motivation to engage in play among SAM children and families facing severe dietary problems. Consequently, the intervention package was less intensive and could not be implemented as planned. Second, the possibility for a contamination effect cannot be ruled out for this study. For ethical reasons, a playground meant for the study was accessible to all children. Moreover, there was a possibility for intervention and control children and their caregivers to stay in the same hospital bedroom and thus share information. Even after discharge from hospital, it was also possible that caregivers shared information, since randomization into control and intervention groups did not take the address of the child into account. Third, the study did not address a specific type of severe acute malnutrition, since enrolment was based on broader admission criteria. Hence, children may have oedematous malnutrition, severe wasting, a combination of both, and/or a combination of stunting and wasting. Therefore, the severity of the nutritional deficiency may have varied among the study subjects. As a result, they may have responded differently to the intervention. An earlier study has indicated that the presence of heterogeneous groups of conditions is a factor that constrains the interpretation of literature regarding severe acute malnutrition, and that the outcome of an intervention depends to a large extent on the quality of the subsequent environment (Sally Grantham-McGregor, 1995). Another limitation of the study is a lack of baseline and end-line information on the child's diet and quality of home environment stimulation.

Regardless of its limitations, the study has some strengths. The involvement of a multidisciplinary team of local and European professionals and practitioners enabled the development of a contextually relevant intervention program integrating theory with practice. Developmental outcomes were assessed using an adapted tool, and another one was adapted and standardized in the study context. The home visits and support provided at an individual family level not only allowed a single caregiver to work with the SAM child, but also with all family members, and in some case immediate neighbours and peer groups. It also provided in-depth qualitative data for a better understanding of the child's real context and the challenges impeding the practical implementation of the intervention program. Besides including children of wider age ranges, it is the first randomized controlled trial attempted to examine the effect of adding psychomotor/psychosocial stimulation in the treatment of SAM children both at the in-patient and the out-patient phases under the real circumstances of different family settings.

In summary, this study has shown that play-based stimulation contributes in the treatment of SAM children under six in low-income settings. Stimulation significantly improved the gross motor functions during the hospital stay, and the fine motor functions after discharge during the home follow-up. Both younger and older children benefited similarly from the intervention. The intervention effect on fine motor functions is, however, small. This could be due to the lack of access to an adequate and balanced diet at home, non-intensive stimulation, the short period of follow-up, and non-adherence by caregivers to strictly implement the home-based stimulation. On the other hand, the positive trends of improvement in other developmental areas show a promising effect of the intervention. It shows the possibility of designing a simple, feasible and cost-effective mechanism to engage families in a low-income context in ameliorating the damaging effect of SAM on young children. Future studies need to find a more efficient model for improving motor, nutritional and mental status of very deprived children. Intervention packages ensuring access to balanced diets and extending longer than six months in duration might be better to uncover particularly the gradual developmental changes in older children.

2.3.6. References

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3

CHAPTER 3: GENERAL DISCUSSION & CONCLUSIONS

General discussion

Severe acute malnutrition is lethal and survival is only 50%. Surviving children continue to face life-long challenges. Their growth may be retarded and development hindered from attaining its full potential. As a result, being successful in life may be more difficult for them compared to persons who have not experienced malnutrition. Since the effects also seem to be transgenerational it is of huge importance to intervene as soon as possible. Studies have shown the potential benefit of early interventions such as psychosocial stimulations in reversing the deleterious effects of SAM (Sally Grantham-McGregor et al., 1994; Sally Grantham-McGregor et al., 1983; Sally M Grantham-McGregor et al., 1997; B. Nahar et al., 2009; Baitun Nahar, Hossain, Hamadani, Ahmed, Grantham-McGregor, & Persson, 2012). However, most psychomotor/psychosocial stimulations were given to children 6-24 months of age, informed by the long-standing view about the first 1000 days from conception as a "window of opportunity period". In those studies, dietary supplementation was ensured through distribution on a regular basis. Moreover, the psychosocial stimulation was given at the age when the child has more frequent contacts with the mother and breast feeding is an essential part of the diet for the child. Nonetheless, it is not well established whether or not recommendations based on such interventional studies can benefit the large number of severely malnourished children over two years of age in home settings, where an age-appropriate, adequate and balanced diet is neither available in the community nor easily accessible for regular supply and distribution. Following up developmental changes arising from an intervention conducted on children in low-income contexts in general, and the severely malnourished ones in particular, is also challenging. This is because of lack of culturally relevant tools to assess child development in general, and a tool particularly suitable to assess the fragile, weak and sick children such as those with SAM. Most studies that have been conducted so far have used Western diagnostic tools that take longer assessment time which causes boredom and less cooperation from child, and evaluation bias. Moreover, the Western tools were used without adapting and standardizing them to local children. As a result, the reliability of information on child development in low-income settings is not well established. The magnitude of developmental problems of the myriad at-risk children in such contexts is so obscured that policy-makers lack evident local data that inspire them to initiate and fund child development interventions as their priority issue. Moreover, results of studies currently serving as evidence for recommending psychosocial stimulation for SAM children are often questioned on design issues, as none of them have so far used a randomized controlled trial (Daniel et al., 2017). Therefore, this doctoral project aimed to examine the effect of play-based family-centered psychomotor/psychosocial stimulation on the developmental and nutritional outcomes of six months to six years of age Ethiopian children with severe acute malnutrition during treatment at hospital and six months of follow-up after discharge from hospital. The study used a randomized controlled trial design, and was conducted in a setting with very poor living conditions: a non-stimulating home environment, inadequate and unbalanced diet, and poor sanitation. Most parents were non-educated and living in rural areas with subsistence agriculture. During the home-based stimulation, the children had not obtained standard nutritional rehabilitation as was the case in hospital. The duration of stay in hospital, however, was relatively short (12 days on average compared to six months of follow-up at home). Trained nurses mediated the developmental stimulation using play materials and toys in a playroom alone, or a playroom and a playground near to the paediatric ward of the hospital. During the home-based follow-up parents, grandparents, and siblings served as caregivers, and mediated the home-based stimulation. The skills were transferred to these caregivers by the intervention nurses during the hospital stay and during three home visits. Though all intervention children were provided basic play materials such as balls and cubes, the stimulation at home was carried out within the constraints of family's own limited resources and time. The developmental outcomes of the children were assessed using two Western child development screening tools that were selected as more appropriate to use on such fragile children. These tools were adapted before use and the adaptation and standardization process of one of the tools is reported in this work. The work also reports the effect of a psychomotor/psychosocial intervention on linear growth, nutritional and developmental outcomes of SAM child in a context of one of the low-income countries: Jimma Zone of Ethiopia. Younger and older children within an early childhood period (3-65 months of age) were involved. Western child development screening tools were adapted to the local socio-cultural contexts for a reliable estimation of the child developmental outcomes. The main findings of this work are: 1) that the age of milestone attainment differs between children of the Western and that of low-income socio-cultural contexts, and that not only adaptation but also standardization for local children is needed before using in non-Western contexts, and that they can be adapted as reliable tools to estimate child development in low-income context; 2) different dimensions of development are delayed in children with severe acute malnutrition, and that there is a differential age effect on developmental outcomes during the acute stage; and 3) that psychomotor/psychosocial stimulation benefits the recovery of gross motor functions during hospital based follow-up, and fine motor functions during the home follow-up.

3.1. Western tools for child development screening can be adapted as reliable tools to estimate development of children in a low-income socio-cultural context

Healthy children are the hopes and bedrocks of a stronger society. Therefore, addressing the holistic health of children through appropriate care and necessary provisions is a profitable investment. One of the crucial steps in the creation of a healthy and prosperous society is working on children on three dimensions: ensuring survival, promoting healthy growth, and stimulating multi-dimensional development. Due attention and closer follow-up is needed for a balanced approach to these three dimensions to ensue holistic child health so that they survive, thrive, and contribute actively to the welfare of their community.

Unfortunately, child health and care systems in low-income contexts usually use child survival as a measure of treatment success and focus on growth outcomes as common indicators. There is a scarcity of child development data obtained through direct assessment. Since children living in poverty are at greater risks that compromise growth, development, and general health, their developmental profiles have been estimated from poverty levels and growth outcomes as proxy indicators (Sally Grantham-McGregor et al., 2007). Services aimed at counteracting the damaging effects of the risk factors are scarce, less comprehensive, lack adequate budgetary allocations and skilled professionals.

Efforts to mitigate the health risks of children in many low-income countries are usually driven by pressure from international conventions, and are highly dependent on foreign aid. Such efforts are often fragmented, benefit very few children, and address only certain aspects of child health. Therefore, there is a dire need for a sustainable and holistic childcare system, which encompasses development, growth, health, nutrition, and feeding practices.

In spite of multiple risk factors impeding child development, much is unknown about the magnitude of child developmental problems in under-developed low-income countries such as Ethiopia. The attention given by the government and general public to the issues of child development is less than what is required, as can be witnessed from inadequately stipulated child health policies and strategies, implementation programs and legal frameworks; inadequate child care centres and child development resources, inadequate child welfare services, and meagre child health and care related research undertakings. Above all, there are no authentic data on developmental profiles of children in low-income contexts due to the lack of culturally relevant child development assessment tools. Few studies have investigated child development using tools developed in the industrialized societies of the West. Being inspired by researchers who wanted to examine the developmental effects of a specific problem (e.g., being stunted, under-weight, HIV/AIDS positive), the studies employed tools developed in Western culture by dropping some culture-specific test items (Aboud & Alemu, 1995; Bhargava, 2000; Drewett et al., 2001; Neumann et al., 1991; Stoltzfus et al., 2001) or without making any adaptations to them (Hokjindee et al., 2010; Lohausa et al., 2011; Nanthamongkolchai et al., 2007). Firstly, the reliability of data obtained in this way is questionable. When fragile, weak, and sick children such as those with severe acute malnutrition are assessed, the reliability of data generated becomes even more questionable. Secondly, most of the studies conducted on the development of children in low-income contexts addressed children of certain ages, mostly those under age of two. Hence, attempts made for adaptation focused on limited areas rather than all test items within a tool. Thirdly, these few studies did not report the developmental profile of children during the hospital follow-up. Most of the studies determined the psychomotor and mental development of children through an in-depth examination using diagnostic tools such as the Bayley Scale of Infant Development: BSID-I (Bayley, 1969) or the later version, BSID-II (Bayley, 1993). Diagnostic tools that require much testing time, however, are not suitable for use on SAM children addressed by the present study, particularly during the hospital based follow-up. Since SAM children are weak, fragile and irritable, conducting an authentic assessment of their developmental performance requires employing child-friendly, simple, and quicker tools that can be used by non-specialists. Therefore, we had two options: developing a new one or adapting and using the existing tools. Since developing an indigenous tool is costlier, a better option is to look for a feasible tool to adapt. Secondly, since screening tools are simpler, quicker and more feasible than diagnostic tools to use on fragile SAM children, we selected and adapted the revised Denver Developmental Screening Test (the Denver II), which was created in the USA (Frankenburg, Dodds, et al., 1992a) (Study 1). By focusing on culture-specific test items, we modified them to the local socio-cultural context through different phases of cross-sectional studies: an exploratory survey, piloting for feasibility in small groups, reliability assessment in small groups, and both feasibility and reliability assessment in large groups. The studies on small groups were conducted using kindergarten teachers and those on large group used clinical nurses as testers. The series of steps followed during this process could be used as a methodological prototype in adapting the same or similar tools for use in other low-income contexts. The reliability of the tool while using different testers (school teachers and clinical nurses) was good, indicating that the adapted tool could be used by different paraprofessionals providing frontline services daily for children in low income contexts. Unlike in some other studies (Aboud & Alemu, 1995; Bhargava, 2000; Drewett et al., 2001; Neumann et al., 1991; Stoltzfus et al., 2001), we did not drop test items in the adaptation process. This helps maintain the content and construct validity of the adapted tool. By standardizing the adapted tool to local healthy, non-malnourished children who were comparatively developing in more optimal living conditions than many other children, we created a reference group against which the development of children at different risks could be compared. The availability of a tool to assess development would incite interventional studies addressing developmental problems. As a result, more studies delving into the developmental outcomes could emerge, adding more dimensions to studies on children in low-income context. The creation of a local standard also enabled us to compare the ages of attaining milestones between the local reference children and the children for which the original tool was standardized. While there is a lack of significant difference between the two groups on the 90 percentile age of passing on most (66.4%) of the test items, the clinically significant difference on the remaining 42 test items are both expected results. As the world is rapidly globalizing with a faster exchange of knowledge and experiences, there is a wider opportunity for similarity in childcare services. Such shared experiences could contribute to the much more similar development outcomes observed among children of similar ages. As variations in socio-cultural practices gradually dwindle through globalization, there would be more homogenization in social practices, lifestyle and childcare practices, leading to a more similar developmental performance among children of similar age regardless of where they are born and living. This has been reflected in our study: the majority of test items used in the Western tool (71.2%) did not need adaptation. On the other hand, individual differences at a family and societal level are unavoidable and could result in variations in childcare practices, which in turn contribute to variations in child development outcomes. It is, therefore, necessary to have a population-specific local standard for a tool to assess child development. Having a local standard avoids the mistakes of over- or under-estimating developmental performances of children when a tool developed and standardized in another context is used without modifying it to the local context. By adapting and standardizing the Denver II to the socio-cultural context of a low-income country, Ethiopia, we are able to show how Western child development screening tools could be modified for a reliable estimation of child development outcomes in low-income contexts.

In the present study, the adapted tool has been used mainly to follow up children already identified as SAM, and hence developmentally at risk. Though the adapted tool was found to have a good reliability, it may suffer from poor specificity, for which the original tool is often criticized. Thus, as a screening tool that could over-identify suspected cases, it is advisable to refrain from labelling a child based on a single assessment result. Ecological assessment should be conducted to examine the child suspected of having a problem in different contexts and at different times. Above all, there is a dire need to have a culturally relevant diagnostic tool.

Though the tool was adapted and standardized in a context of multicultural and multilingual Ethiopian communities, it should not be used without optimizing it in other specific cultural contexts. As Ethiopia has more diverse communities with different cultures, traditions and languages, further optimization of the tool in different settings is needed before using it in a context other than the one for which it is standardized. In this case, future work has to be on optimization of the tool on selected larger communities with shared social and cultural values and practices.

In summary, we can conclude that a child development assessment tool developed and standardized in a Western socio-cultural context can be adapted as a reliable tool for use in a non-Western, low-income context. In order to have a reliable assessment of the performance of a child in relation to other children of equal ages living in a similar socio-cultural context, standardizing the tool for the local population is crucial. A screening tool, rather than a diagnostic tool is more suitable for adaptation and standardization because it can easily be used by paraprofessionals in low-income contexts. Screening tools do not require specialized training for administration, and are more cost-effective and suitable to use in the low-income context where specially trained human power is scant. The selected screening tool is child-friendly, quicker and simple to follow up fragile children such as the severely acutely malnourished ones in both non-clinical and clinical settings. Specificity, sensitivity, and concurrent validity of the tool need to be established in comparison with a tool which provides in-depth information through specialist assessment. Future studies on the developmental assessment of children in a low-income context should address adaptation of diagnostic tools for further scrutiny of children screened as suspected of having developmental delays.

3.2. Developmental performance in children with severe acute malnutrition is differently affected among children of different ages

Many studies on SAM have targeted hospitalized children. They have compared the developmental performance of SAM children with that of non-malnourished siblings or age-mates hospitalized for illnesses other than malnutrition (Sally Grantham-McGregor et al., 1982; Sally Grantham-McGregor, Stewart, & Powell, 1991; S. M. Grantham-McGregor, M. Stewart, & P. Desai, 1978). Though such studies have tried to control the effect of hospitalization, their study design did not allow them to randomize and match the comparison groups on all other factors. The studies did not match the SAM group with the comparison group on their developmental characteristics before the incident of the acute malnutrition. Hence, such studies do not enable the attribution of a causal interpretation to SAM. Other studies have retrospectively uncovered developmental deficits in the later life of children who had experienced SAM (Bartel et al., 1978; J. Galler et al., 2010; J. R. Galler et al., 1990; Janina R. Galler et al., 1987a, 1987b; Hoorweg & Stanfield, 1976). Though such studies have helped in understanding how children that were exposed to SAM perform on developmental tasks later in life, they did not show what happens to the following during the acute stage: (a) the degree to which the developmental performances are reduced, (b) which dimensions of development are hampered more severely, and (c) whether or not the effects are different for children of different ages. The present study (Study 2) compared the SAM children during the acute stage of the incident with that of age- and gender-matched non-malnourished, non-hospitalized healthy children between three and 65 months of age on five dimensions of development. The study has shown that SAM children are affected differentially in different domains of development based on their ages. The highest delay on all the domains of development is during early life. Developmental performance of one-year-old SAM children is delayed the most on gross motor followed by fine motor skills, but the least on language performance. The severity of the delay decreases with an increase in age. The delay at the age of one by 300% and 200% on gross motor and fine motor is reduced to 80% and 50% respectively at the age of three. Though smaller at older ages, the motor skills remained relatively the most affected skills throughout all ages. Since SAM seriously affects the muscle mass, it is expected that the delay in gross motor skills is the most severe of all. The delay in personal-social performance gets smaller than that of language performance as age of children increases. In general, the study shows that SAM affects the development of younger children more seriously than that of older ones. This is more damaging since the earlier ages are more critical in laying foundation for later life. This is also a time when children are not well understood by most caregivers. It is a time when more professional support is needed to make parents understand children's needs and development in order to contribute effectively and efficiently in providing early intervention that benefits their child. In Ethiopia, this is a big challenge, as there are neither adequate professionals nor a system that provides parents access to early intervention services.

Within the SAM group, the strongest correlation was observed between language and personal-social functions compared to the correlation of each one of these with the motor functions. Within the group of healthy non-malnourished children, the strongest correlation is between personal social and gross motor functions. Language is more strongly correlated with fine motor than gross motor skills in both the non-malnourished and the SAM children. These relationships might imply that: 1) for the SAM children, activities that enhance personal-social and the language functions are complementary and reinforce each other, but for the healthy ones, the gross motor skills and the personal-social skills reinforce each other; 2) activities that enhance fine motor and language skills can reinforce each other regardless of the nutritional status of the child; 3) the SAM children seem to benefit less in gross motor skills from activities that enhance other skills. Interventions that purely target language and personal-social functions of the SAM children may have less contribution in enhancing their gross motor functions. It also seems that the correlation of language with motor skills depends on socio-economic status. For example, a correlation study between language and motor skills (fine and gross motor) on Ethiopian children showed a stronger correlation of language with fine motor skills than with gross motor skills in children from a low socio-economic status, a stronger correlation of language with gross motor skills than with fine motor skills in children from a higher socio-economic status (Materu, 2016). The social-emotional and motor skills are more seriously affected among younger and older age children. Younger SAM children are also more delayed than older ones on all the domains of development (FM, GM, LA and PS). The degree of the delay generally decreases with an increase in age. This finding is consistent with the argument that infants and children are the most vulnerable to the effects of undernutrition because early age is the period of most rapid physical growth and development, the period of extra nutritional requirements for growth and development, and a period when their bodily energy reserves are smaller (Picot et al., 2012). The finding strengthens the already existing view about the importance of early intervention and giving due attention to younger SAM children during rehabilitation services. On the social-emotional development, more attention is needed also for older children. Across all ages, motor skills remain more seriously compromised and therefore require interventions that focus more on strengthening them.

In brief, the present study has shown that different dimensions of child development are seriously affected among SAM children of different ages during the acute stage of severe malnutrition. The rehabilitation of SAM children should therefore target strengthening all the different domains of child development. In addition to medical treatment to counteract illnesses associated with malnutrition, an equally important intervention is rehabilitating the different developmental functions of the SAM child that are compromised. Dietary therapy and age-appropriate psychomotor/psychosocial activities which integrate the different domains of child development are essential. Good nutrition can help children prepare themselves to receive optimal psychosocial stimulation. When children get diets that keep them energetic and maintain their bodily functions, they naturally like to engage in play. Caregivers can build on such natural desires and enrich the contents of the child play to address the different dimensions of development. Age-appropriate psychomotor activities may enhance the recovery process of SAM children by increasing their dietary intake, and improving their body physiology and functions. Access to a balanced diet during this stage not only contributes to rebuilding the body muscles and strengthening the immune system, but it also optimizes the physiological functions and different systems of the body and speeds up the recovery process. Lack of a balanced diet, on the other hand, would slow down the recovery process. This seems to be evident from the significant improvement in gross motor functions during the stay in hospital where there was strict dietary treatment but not after discharge during follow-up at home (study 3). Unlike at the hospital, there was neither regular provision of a supplementary diet, nor was there an adequate and diversified diet available for children during the home follow-up.

The study shows that the development of SAM children is more seriously affected during very early life. SAM children live mostly in poor contexts where the poverty level is high. Unfortunately, comprehensive childcare systems and early intervention services are lacking in such contexts where they are deemed important. A multi-sectoral approach is needed to fight poverty, malnutrition, and child health problems. Holistic early intervention services grounded in scientific evidence need to be provided through collaborative programs that combine child health, care, and education. The dietary treatment and psychomotor/psychosocial activities have to be integrated to the daily routine of childcare practices. However, such actions are inconceivable without the involvement of all stakeholders working with children. A clear policy direction and strategic goals, programs for implementation, a fair budget allocation, and legal regulatory frameworks to monitor and evaluate early intervention services for children are needed for holistic transformation of a nation from the grassroots level.

3.3. Play-based family-centered psychomotor/psychosocial stimulation benefits the developmental recovery of SAM children in a low-income context

Interventional studies conducted on SAM children admitted to hospital have tried to control the effect of hospitalization (Sally Grantham-McGregor et al., 1994; Sally Grantham-McGregor et al., 1987). Such studies could not control other factors because they did not match comparison groups when they were in hospital on account of ethical issues related to randomized allocation to differential services. This has often led results to be interpreted with limitations such as allocation bias. Second, since such studies addressed children from 6-24 months of age, they have shown the effect of psychosocial stimulation on the development of SAM children mainly in situations where dietary rehabilitation is ensured through supplementation and maternal breastfeeding. Much is unknown about the effect of psychomotor/psychosocial stimulation offered to SAM children of older ages in general, and those who neither get adequate supplementary diet nor basic food services in the family during the stimulation, in particular. The present study employed a randomized controlled trial design and investigated the effect of play-based family-centered psychomotor/psychosocial stimulation on linear growth, nutritional, and developmental outcomes of children between six months and six years of age. It has shown that the intervention significantly improved the gross motor functions only during stay in hospital, but the fine motor functions, after discharge from hospital. Though the stay was shorter, the hospital was better in many respects than the poor home setting to which the SAM children were returning for a longer follow-up. The hospital provided better sanitation, play facilities and high-frequency stimulation, a balanced diet, more frequent contact with caregivers on daily basis. A provision with the same quality and intensity could not be continued at the home setting of the present study. On one hand, the stay at hospital was too short to see a significant effect of the intervention on the various domains of child development. On the other hand, the home-based parent-mediated psychomotor/psychosocial intervention was not provided with the same intensity and quality as the hospital-based intervention. This could result in a slower and a latent effect of the intervention since developmental changes are often gradual. As a result, there is a possibility that the language and personal-social functions could improve over time. Long-term follow-up on Jamaican children with SAM have shown that the intervention SAM group performed significantly higher than the control SAM in language (Sally Grantham-McGregor et al., 1994; Sally Grantham-McGregor et al., 1983). When a psychosocial intervention was given for a period of two years for low-birthweight infants until they were two years of age, its effect was sustained, and at the age of six years, the intervened children performed higher on IQ scores and exhibited less behavioural difficulties compared to the low-birthweight control children (Susan P Walker, Chang, Younger, & Grantham-McGregor, 2010). With a longer follow-up, there is a possibility for the intervention in the present study to produce a significant effect. Yet prolonging the duration of follow-up may not bring a desired effect on the child in the absence of a basic diet required for daily life functions of the SAM children. It could, however, strengthen the caregivers' capacity to effectively contribute to child development by improving parenting skills and the mothers' knowledge and practices of childrearing (Hamadani, Huda, Khatun, &

Grantham-McGregor, 2006; Powell, Baker-Henningham, Walker, Gernay, & Grantham-McGregor, 2004).

Inconsistent findings have been reported on the effect of psychosocial stimulation on motor development of severely acutely malnourished children (Daniel et al., 2017). At two years of follow-up, psychosocial stimulation did not have a sustained effect on gross motor skills. On fine motor skills, the intervention group remained significantly ahead of the malnourished control group at the three–, four–, and five–year follow–up times, and scored similarly to the non–malnourished children (Daniel et al., 2017). The inconsistency in findings is also observed on nutritional outcomes. The psychomotor/psychosocial intervention in our study did not contribute significantly to improving nutritional outcomes determined in terms of HAZ, WAZ, WHZ and MUACZ scores. Like our study, some earlier studies have shown a lack of effect on nutritional outcomes (Sally Grantham-McGregor et al., 1983; Hamadani et al., 2006), but others have shown a significant increase in weight-for-age-z score after six months of follow-up (B. Nahar et al., 2009; Baitun Nahar, Hossain, Hamadani, Ahmed, Grantham-McGregor, & Persson, 2012). Except one study that made a follow-up for 2 years (Sally Grantham-McGregor et al., 1983), the others evaluated the effect after six months of follow-up. The studies targeted children between 6-24 months of age. Our study, however, included children from six months up to six years of age, since the effect of psychomotor/psychosocial stimulation on SAM children above two years of age has not often been studied. The findings to date are inconclusive and, therefore, further studies are needed. In low-income countries where many children under five often suffer from SAM, little is known about how much SAM affects children older than two years of age. There is not much evidence of older children benefiting from the psychosocial stimulation recommended in the management of SAM children. Though children of six months to six years of age were included in our study, the intervention effect was found to be independent of the age of the child, implying similar benefits for both younger and older children from the psychomotor/psychosocial intervention. Though younger children were found to be more affected than older ones (Study 2), they did not differ from older children in responding to the intervention. On the other hand, study II showed that the gross motor and the fine motor functions remain the skills most seriously affected across different ages. The fact that these two skills responded to the intervention may show that the development most affected seems to benefit from the intervention. Though the difference was non-significant on LA, PS and SE, the intervention SAM children generally performed better than the control SAM on four domains of development (GM, FM, LA and PS) and showed lower behavioural problems. Duration of follow-up, being a significant predictor of all developmental outcomes of the intervention children, implies the possibility of obtaining a significant intervention effect by increasing the shorter time of follow-up (an average of 10 days in hospital and six months at home after discharge from hospital). On outcomes with a positive trend of improvement, as observed during home follow-up (gross motor, language and personal social), the intervention effect is likely to be significant if the follow-up time is prolonged like it was in earlier studies. More understanding is needed through intervention research with a longer follow-up period on larger samples of SAM children of different ages. Though an attempt was made to control various factors through a randomized controlled trial, the present study may not be free of contamination bias since complete control was not possible for ethical and practical reasons. Both the control and the intervention SAM children shared the same bed room and had access to stimulation facilities in hospital. There is a possibility for experience sharing among caregivers of the intervention and the control SAM children living in closer vicinity. More research evidence is needed to inform actors in the healthcare sector about the most feasible psychomotor/psychosocial stimulation practices in the treatment of SAM children. Research evidence on the short- and long-term effects of psychosocial stimulation on SAM children comes from fourteen years follow-up studies conducted by Grantham Mc-Gregory et.al. on Jamaican children admitted to hospital with SAM. These studies are often considered seminal works that, in 1999 served WHO (WHO, 1999) to recommend a psychosocial stimulation in the treatment of SAM children. Yet the studies are criticized for high risk of selection bias, not using culturally validated and locally standardized development assessment tools, and for testing a less feasible intensive intervention that lasts as long as three years (Daniel et al., 2017). More randomized controlled trials taking age and sex of children, residential areas (urban/rural), maternal education and socio-economic status into account are needed. There should be mechanisms to control potential contamination bias that could arise from diffusion of information among control and intervention families about the psychomotor/psychosocial stimulation.

An important issue worth discussing is the effectiveness of the intervention model used. The intervention framework recommended by ICF combines both the medical and psychosocial models of treating diseases and disabilities. The psychomotor/psychosocial intervention was undertaken within contextual factors such as the real economic, cultural, and physical context of each family of the SAM child through the participation of caregivers and in the form of play-based activities and daily routines. Yet, this model does not seem to have been effectively implemented due to contextual factors such as grave nutritional deficits that continued to prevail, and the multiple roles and commitment of caregivers. Caregivers' lack adequate time to work with the SAM child. A SAM child lacks even the basic diet needed for survival and daily functions, let alone a balanced diet. The dietary deficits reduce children's motivation to play and engage actively in different psychomotor /psychosocial activities that would enhance their growth and development.

The psychomotor/psychosocial element of our study can be scaled up. Child developmental stimulation services is now a part of the child health care at Jimma University Hospital. A playroom furnished with different play materials provides services at a paediatric ward, where two nurses fully engage in rendering the services. Not only SAM children, but also other children are referred to the playroom for play therapy. Children and caregivers like the playroom because it is a place where the children smile and caregivers see a glimpse of hope in their children, who are often irritated or depressed after pains of illness and some intensive procedures. Caregivers are shown how to provide different types of sensory stimulation not only to the SAM children, but also other children referred to the playroom by physicians. For the management of SAM, a 20-30 minute caregiver training and provision of simple play materials on discharge could contribute much in reversing the damaging effects of SAM. The idea of play-based stimulation can be implemented on a large scale in the current Ethiopian health care system. As there are two health extension workers at each local administrative unit called Kebele, it is possible to provide them with training on developmental stimulation. Since the health extension workers always make visits to home of each family, they can provide continual support.

3.4. Concluding remarks

Development outcomes are comparatively less studied than growth outcomes in children of low-income countries. This is mainly due to a lack of culturally relevant child development tools. Few studies have examined development outcomes among a specific age group of children by adapting only some test items within a tool. Such test items, however, were not standardized for local children, and may not accurately reflect the child development outcomes within the specific socio-cultural context. This thesis presents three studies describing the developmental performances of children in a low-income context. The first study is about the adaptation of a child development tool with the objective of making it culturally relevant to use on children under six in a context other than where it was originally created. The study has shown that the age of attaining milestones on the adapted tool differs from the age of attainment on the original tool, and that a child developmental assessment tool created in a given socio-cultural context not only needs to be adapted, but also standardized for the local child population on which it is to be used. Since children with severe acute malnutrition were targeted for study, the selection of a tool for adaptation considered the nature of SAM children (being weak, fragile and easily irritated) and real situation of study context (scarcity of specially trained professionals). Screening tools are more suitable than diagnostic tools to be used on weak and fragile children such as those with SAM, and can also be administered easily and quickly by less trained personnel and paraprofessionals. The study depicts how a Western child development screening tool can reliably be adapted and standardized for use in a non-Western cultural context. The second study compares the developmental performances of SAM and healthy children under six and has shown that: (a) SAM children performed significantly worse than age- and sex-matched healthy children; (b) younger SAM children are more seriously affected than older SAM children; (c) motor skills (gross and fine motor) of SAM children are more affected than their language and personal-social skills. The third study evaluated the effect of play-based psychomotor/psychosocial stimulation on the recovery of SAM children using the adapted tools and has shown that: (a) the psychomotor/psychosocial stimulation significantly benefited: (i) the recovery of gross motor functions during a hospital based follow-up time; (ii) the recovery of fine motor functions during the home-based follow-up time; (b) psychomotor/psychosocial stimulation benefits both younger and older SAM children similarly. The study shows the importance of psychomotor/psychosocial stimulation for the recovery of SAM children and proposes a further randomized controlled trial study examining the effect of more intensive stimulation and longer-term follow up time by ensuring stricter control of contamination bias arising from possible contacts and experience sharing between control and intervention SAM children.

3.5. Strengths, limitations and future perspectives

3.5.1. Strengths of the current studies

This is the first randomized controlled trial that has attempted to investigate the effect of psychomotor/psychosocial stimulation at both a hospital and home-based situation in a resource-poor setting on the recovery of SAM children of a wider age range. The other strength is that the study used culturally relevant developmental assessment tools to make reliable estimates of developmental outcomes. The intervention was implemented in a real situation reflecting the complex context of intertwined problems in addressing child malnutrition in a low-income country. The findings and recommendations given are therefore more authentic than those of studies in controlled situations, and could easily be scaled up for use in similar situations.

3.5.2. Limitations of the current studies

In the standardization of the adapted tool, only children from better income families living in urban areas were included. Though children from different cultural, ethnic, linguistic, and religious communities were included, they all live in a similar socio-cultural environment with many shared traditions, values, beliefs, and practices. Therefore, they may not be typical representations for each group. Consequently, we neither conducted sub-group analysis, nor examined if children differ in age of attaining milestones based on such grouping variables. Future work has to examine the milestones attainment ages in children from these different groups. Though developmental screening tests are essential and can be used with paraprofessionals on population-based studies, they may not accurately determine if a child is suspected or really delayed developmentally. While comparing the developmental performance of SAM children with that of healthy children, it was not possible to single out the effect of hospitalization and pre-natal risk factors from the net effect of the severe acute malnutrition. There was no baseline information if the SAM and the healthy children had had a similar developmental profile before the incident of the acute malnutrition. The SAM and non-malnourished healthy children differed on many factors other than nutritional status. Therefore, differences in developmental performance between the two groups cannot be attributed solely to severe acute malnutrition. The present study merely depicts how much the developmental performance in SAM children is delayed compared to non-SAM children. Explaining the delays as a sole function of SAM introduces a biased estimation. While conducting the intervention study, it was not possible for ethical reasons to deny the control SAM children from accessing a playground meant for the intervention SAM children. Moreover, it was not possible to avoid contact between the control and the intervention groups. In some cases, children from both groups were sharing the same bedroom during their stay at hospital. During randomization, there were chances for some children from the same locality to be assigned to different treatment groups. As a result, even after discharge from hospital, there was no mechanism to ensure that caregivers of the intervention and the control children were not sharing experiences. Hence, it is difficult to absolutely rule out the possibility of contamination of the intervention effects. This might have affected the outcome of the study, particularly the size of the intervention effect. Finally, a home-based follow-up time of six months might not be enough to uncover gradual developmental changes.

3.5.3. Future perspectives

The more wisely and carefully a society invests in its children, the more it reduces a loss of its potential human capital, the more it intensifies its success, prosperity and well-being. Propelled by a momentum from the Millennium Development Goals, commitment and engagement of the government, non-governmental organizations, and overseas development assistances, there has been a considerable improvement in child health in Ethiopia over the last two decades. The mortality rate of children under-five child decreased from 205 deaths per 1,000 live births in 1990 to 59 deaths per 1,000 live births in 2015 (UNICEF, 2016). However, child malnutrition still remains a major child health challenge. Though the prevalence of under-five stunting and underweightness respectively has declined from 58 and 41 percent in 2000 to 38 and 24 percent in 2016, the percentage of wasting declined from 12 to 10% during the same period (Central Statistical Agency [Ethiopia], 2016), indicating the lack of much improvement in this regard. Malnutrition is inter-linked with diverse and complex causes such as low dietary intake resulting from lack of food or unbalanced distribution of food among family members, and recurrent infections associated with poor personal and environmental sanitation and inadequate water supplies, and unavailability or low utilization of basic health services (Ethiopian Federal Minstry of Health, 2008). Tackling malnutrition, therefore, requires addressing such multifaceted causes from various perspectives using different means. One means is improving maternal knowledge and skills about nutrition, and improving the nutritional status of mothers. Without ensuring women’s nutritional status and health, child health cannot be guaranteed. In Ethiopia, little improvement was seen in women’s nutrition over the period of 2000-2015 (Ethiopian Ministry of Health/UNICEF/EU, 2016). Thinness and anaemia remained a major concern for women. It is, therefore, important to set a double goal of improving both maternal and child nutritional status. An integrative approach is needed to ensure holistic child health and maternal care. This requires commitment for resource mobilization and a fair allocation of budget, raising public awareness about the current health status of women and children, and revealing the potential gains of investment on women and children’s health in building strong and prosperous society.

The success achieved in reducing child mortality has to extend to improving survivors’ quality of life. Child and maternal health should be one of the strategic government priorities defined with contextualized policy, strategy, and enforcement laws. Carefully developed proactive plans are needed, rather than haphazard reactive measures taken to meet demands of external pressures such as international conventions and donor-driven policies that might not align with the local cultures and community values. There is a dire need for research to examine existing experiences and traditions, synthesize and publicize up-to-date knowledge and scientific breakthroughs on the best early child care practices. The multi-sectoral and holistic early childhood care and development policy and implementation strategies are a positive step forward. However, much needs to be done to materialize the policy ideas. Child health and care policy, strategies and programs are needed to address current gaps related to the lack of professionals adequately trained in child care, assessment and intervention. There should be a fair allocation of government budget and a shift from dependency on donor-driven financing and ownership of child and maternal health programs. Measures are needed to encourage research and investment on the adaptation and creation of culturally relevant and local standard tools for early screening, assessment, and diagnosis of child developmental problems. Though adaptation of a Western tool to the socio-cultural context of a non-Western context is a commendable work, attention has to be given to ensure its validity, reliability, specificity and sensitivity. It is speculated that the weak specificity of the original tool may still be part of the weakness of the adapted tool. In the present study, the specificity and sensitivity of the adapted tool was not determined due to lack of a gold standard diagnostic tool serving as a reference. Hence, future work should aim to adapt a diagnostic tool that would be culturally relevant to use, and determine the sensitivity and specificity of the adapted screening tool against a reliable diagnostic tool. Effective health monitoring and evaluation requires integrating maternal and child health care systems. It necessitates documenting maternal conditions at a prenatal stage, and conducting mandatory periodic assessment and documentation of each child’s growth, nutritional, and developmental profiles starting right at birth. Future studies that have to examine the extent to which growth, development, and nutritional outcomes are affected in SAM children should control the effects of risk factors other than malnutrition. Determining the net effect of SAM requires the comparison of the developmental performances within the population of SAM children by categorizing them into two groups: those with, and without developmental delay. This means that standardized cut-off scores would be used for comparison rather than a relative performance score by the healthy children (the case in the present study). Future studies also need to control for the effect of hospitalization by enrolling SAM children after they are discharged from hospital. Baseline differences in developmental performances need to be controlled by matching participants on sex and age, and on their developmental profile before the onset of the acute malnutrition. This would give an insight into the net effect of SAM. Some developmental changes may be slower and need longer than the six months' follow-up period in the present intervention study. Future randomized controlled trials aimed at assessing the effect of psychomotor/psychosocial stimulation on SAM children have to control the effects of length of follow-up, intensity of stimulation, and contamination bias through careful study design. Since the implementation of family-based stimulation has encountered challenges such as caregivers' multiple family responsibilities and lack of adequate and balanced diet for the SAM child, the intervention was not executed as per protocol. Future work needs intervention model or package to be designed that is more feasible and effective to implement at each family level in a context where poverty and child malnutrition continues to prevail.

In conclusion, the prosperity of a nation is inconceivable without the health of its children. Though children in low-income contexts are exposed to a myriad of risk factors that hamper their growth and development, they do not have adequate services which mitigate the damaging effects of such risk factors. The few available services are fragmented and are run by non-governmental organizations such as private business owners or by charity organizations. Such services benefit only a few sections of society: the rich who can afford to buy available services, and the very few destitute who are supported by charity organizations. In most cases, such services are neither based on the latest scientific evidence, nor carried out by properly trained personnel. The services are not comprehensive and rarely combine activities that enhance child survival, growth, and development. Therefore, there is a dire need to evaluate and improve available child service programs. Attention needs to be given to child care, nutrition, health, and education. Early identification of child health problems and appropriate interventions are needed. The focus has to be on holistic childcare, addressing multidimensional aspects: growth, health (physical strength, mental alertness, emotional security, social competency and readiness to learn) and development (cognitive, emotional, motor, language and communication, personal-social, social-emotional, etc.). Health professionals, paraprofessionals, kindergarten teachers and others working with children on the frontline need to have adequate theoretical knowledge and practical skills in screening, assessing, and monitoring child development. This requires evaluating existing services, facilities, and programs for children. Health and education institutions in the country should make child health, care, and education issues a joint responsibility and put developmental screening, assessment, and early intervention at the top of the agenda of their programs and services. Child development assessment and intervention has to be integrated into the available health and education services, and exercised practically to give flesh and bone to the narratives of politicians and academicians. A strong legal framework which enforces the development and implementation of comprehensive childcare services need to be in place. Primary healthcare workers and kindergarten teachers need to receive orientation and training on how to conduct developmental screening and assessment, and provide timely interventions. The Ethiopian Government's Early Childhood Care and Education policy framework and multi-sectoral implementation strategies developed in 2010 is commendable. Yet its level of implementation is far below expectation. More action and commitment are needed: clear job structures and functions at different levels, evidence-based childcare programs with strong financial allocation and monitoring, clearly stated duties, responsibilities and obligations for different stakeholders, and enforcement laws.

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4

CHAPTER 4: NEDERLANDSTALIGE SAMENVATTING

Ernstige acute ondervoeding (SAM) bij kinderen blijft een sterk aandachtspunt in ontwikkelingslanden. Kinderen die de ondervoeding overleven vertonen een ernstig risico op ontwikkelingsproblematieken. Zij zijn erg zwak en passief en missen hierdoor heel wat leer- opportuniteiten en sociale interactie, essentieel voor hun ontwikkeling.

Een van de vernieuwende aanbevelingen uit de WHO richtlijnen voor de behandeling van SAM-kinderen, is het integreren van ontwikkeling-stimulerende activiteiten binnen de voedingsrevalidatie (Ashworth et al., 2003). Het doel hierbij is tweevoudig: counteren van het psychomotorisch/psychosociaal deficit alsook het sneller bevorderen van appetijt en gewichtstoename bij de kinderen. Binnen de recente veranderingen in de behandeling van SAM-kinderen (i.e. verschuiving van de ziekenhuis naar de thuis-setting en een primaire focus op voedingssupplementen), werd dit aspect binnen de behandeling bijna volledig overzien.

Hoewel aangegeven door de WGO (wereld gezondheidsorganisatie) als belangrijk, is het effect van het integreren van ontwikkeling-stimulerende (psychomotorische/psychosociale) activiteiten weinig gedocumenteerd. Momenteel zijn maar twee studies op SAM-kinderen beschikbaar (Daniel et al., 2017). Beide studies zijn geen RCT's (randomised controlled trials). Een studie werd uitgevoerd in Bangladesh met een follow-up periode van 6 maanden; de andere in Jamaica met een follow-up periode van 14 jaren.

Nahar et al (2008) rapporteerden een positieve impact op zowel groei en ontwikkeling als gevolg van het integreren van een psychosociale stimulering in de behandeling van SAM-kinderen in Bangladesh in de ziekenhuis- en de thuissetting (B. Nahar et al., 2009). De eerdere studie van Hamadani et al (2006) suggereerde echter dat psychosociale stimulering, in combinatie met de voedingsrevalidatie, enkel ontwikkeling verbetert en niet groei (S. Grantham-McGregor, Stewart, Powell, & Schofield, 1980; Hamadani et al., 2006). Reden hiervoor kan zijn dat in deze studie zowel kinderen met ernstige als gematigde ondervoeding werden opgenomen. (B. Nahar et al., 2009) daarentegen beperkte zich tot kinderen met ernstige acute ondervoeding. De bewijsvoering die de aanbeveling ondersteunt om SAM-kinderen een psychosociale stimulering aan te bieden is niet enkel beperkt, maar ook van lage kwaliteit wat betreft de

belangrijkste uitkomstmaten. De auteurs doen dan ook een oproep naar kwalitatieve RCT's om de effecten van dergelijke interventies na te gaan.
Bovendien is er ook weinig informatie over de grootte van het effect van SAM op de ontwikkeling van kinderen in 'low income' landen. Dit is vooral te wijten aan een gebrek van cultuurrelevante en betrouwbare instrumenten om de ontwikkeling op een correcte manier te evalueren. Bovenvermelde studies geven bijvoorbeeld geen informatie of de Westerse instrumenten om ontwikkeling te testen aan de specifieke socio-culturele context werden aangepast. Westerse testen verschaffen immers mogelijk misleidende info indien gebruikt in andere culturen. Bovendien worden sommige test-items als vreemd ervaren door andere culturen en kunnen ook de normwaarden verschillen van Westerse kinderen. Verder is ook niet bekend of oudere SAM- kinderen voordeel kunnen halen uit een dergelijk stimuleringsprogramma. Bovenstaande studies hebben zich beperkt tot kinderen tussen 6 en 24 maanden oud. Kinderen ontwikkelen nochtans gedurende de eerste 5 jaren. Vermits het aantal van ernstige acute ondervoede oudere kinderen aanzienlijk is, is het ook nodig dat het effect van ondervoeding op deze kinderen wordt gemeten.

Het hoofddoel van deze doctoraatsstudie is daarom te documenteren in hoeverre spel-gemedieerde en familie-gecentreerde psychomotorische/psychosociale stimulering de effecten van SAM op kinderen in 'low income' situatie, waar voedingsrevalidatie in de thuissituatie een enorme struikelblok blijft, kunnen counteren. Vandaar dat de thesis drie studies documenteert:
(1) de adaptatie en standaardisatie van een Westers instrument tot een cultureel relevante test voor gebruik in een niet–westerse setting
(Central Statistical Agency [Ethiopia], 2016) de inschatting van de ontwikkelingsachterstand van kinderen door SAM, gebruik makende van deze aangepaste instrumenten, en tenslotte
(3) het effect van psychomotorische/psychosociale stimulering op ontwikkeling met behulp van deze cultureel relevante instrumenten.
De drie studies werden uitgevoerd in de Jimma regio in ZW-Ethiopië. Zowel gezonde als ernstig acuut ondervoede kinderen onder zes jaar werden hiervoor bestudeerd.

De eerste studie van de adaptatie en standaardisatie van de westerse ontwikkelingstest Denver II laat zien dat 36 van de 125 testitems dienden aangepast te worden om relevant te zijn voor de culturele context in Ethiopië (Abessa et al., 2016). Standaardisatie van deze aangepaste test op 1597 gezonde kinderen (tussen twee dagen en zes jaar oud) laat zien dat de leeftijd voor het bereiken van de mijlpalen voor de Jimma kinderen verschilt van de leeftijd aangegeven in het oorspronkelijk instrument. Instrumenten opgesteld in een gegeven context dienen dus niet enkel aangepast te worden maar ook gestandaardiseerd op de lokale populatie waarvoor zij worden gebruikt. De studie laat ook zien hoe een Westers screening instrument voor de ontwikkeling van kinderen op een betrouwbare manier kan worden aangepast en gestandaardiseerd voor gebruik in een niet- Westerse context.

Dit aangepast instrument wordt vervolgens gebruikt in de tweede studie om de ontwikkeling van 310 SAM- kinderen jonger dan zes jaar met die van 310 gezonde kinderen (met vergelijkbare leeftijd en geslacht) te vergelijken. Het blijkt (a) dat SAM-kinderen beduidend slechter scoren dan hun gezonde leeftijdsgenoten (b) jongere SAM-kinderen meer beinvloed zijn dan oudere SAM-kinderen, en (c) dat bij SAM-kinderen grof- en fijn-motorische vaardigheden meer beïnvloed zijn dan taal en persoonlijke sociale vaardigheden (Abessa et al., 2017). De gerandomiseerde gecontroleerde interventiestudie als derde stap evalueert vervolgens, gebruik makende van de cultuur-aangepaste instrumenten, of spel-gemedieerde familie-gecentreerde psychomotorische/psychosociale stimulering de ontwikkeling, groei en nutritionele status van SAM-kinderen kan verbeteren. Hiervoor werden 339 SAM-kinderen onderzocht met een leeftijdsinterval variërend van 6.1 tot 65.7 maanden, afkomstig uit verschillende districten van de Jimma-zone en opgenomen in het gespecialiseerde gerefereerde 'Teaching' ziekenhuis van de Jimma Universiteit voor medische en nutritionele behandeling. Deze SAM-kinderen werden ad random toegewezen aan een controle (n=170) en een interventiegroep (n=169) en kregen allen de standaard medische en nutritionele behandeling. De interventiekinderen kregen in het ziekenhuis bovendien een psychomotorische/psychosociale stimulering. Deze laatste werd in het bijzijn van de ouders door opgeleide verpleegsters in een educatieve speelkamer binnen en/of buiten in een educatieve speeltuin aangeboden. Aan de ouders zelf gaven de verpleegsters educatie in kindverzorging, voedingsadviezen en praktische adviezen voor wat de stimulering zelf betrof. Na ontslag uit het ziekenhuis werden ook andere familieleden betrokken bij de stimulering. De stimulering betreft dus zowel het kind (psychomotorische) alsook zijn omgeving (psychosociale). De stimulering werd dan verder gezet in de thuissituatie dmv drie huisbezoeken in een periode van zes maanden. Lineaire groei, voedingsstatus en ontwikkeling werden getest aan de start van de interventie, bij ontslag uit het ziekenhuis en na zes maanden in de thuissituatie.

Resultaten tonen aan dat de psychomotorische/psychosociale stimulering

(a) de grof-motorische functies gedurende het verblijf in het ziekenhuis verbetert;

(b) in de thuissituatie de fijn-motorische functies verbetert;

(c) evenveel positief effect heeft bij zowel jonge als oudere kinderen, jongens of meisjes, of kinderen met minder of meer psychomotorische/psychosociale bagage bij de start van de studie; (d) resulteert in een sterkere verbetering in fijn-motorische ontwikkeling voor SAM-kinderen die bij aanvang van de interventie een betere lineaire groei vertoonden

(e) geen effect heeft op lineaire groei en nutritionele status: vergeleken met controlekinderen blijken interventiekinderen die bij de start van de interventie een betere voedingsstatus vertonen, te verbeteren wat betreft de voedingsstatus hoewel hierdoor toch geen verbetering waargenomen werd in de ontwikkelingsuitkomstmaten.

Wanneer de psychomotorische/psychosociale interventie gecombineerd werd met dagelijks een evenwichtige voeding zoals in het ziekenhuis, blijkt de grof-motorische ontwikkeling significant te herstellen. Gedurende de relatief langere follow-up periode in de thuissetting wanneer de kinderen geen toegang hebben tot evenwichtige voeding, was de verbetering enkel significant in de fijn-motorische vaardigheden. Nochtans is er wel een trend van verbetering in taal, persoonlijke sociale en socio-emotionele functies. De duur van de follow-up bleek een significante predictor van alle ontwikkelingsuitkomstmaten, en toont de mogelijkheid aan dat een significant interventie-effect mogelijk is door de duur van de follow-up thuis te verlengen.

Samengevat, toont deze studie aan dat in een 'low income 'setting waar kindzorg en voeding niet evident zijn, spel-gemedieerde kind-gecentreerde psychomotorische activiteiten, samen met psychosociale activiteiten gericht op de directe sociale omgeving van het kind, zeker kunnen bijdragen tot het herstel van de ontwikkeling van SAM-kinderen. Deze studie beveelt verder een vervolg RCT aan om het effect te evalueren van een meer intensieve stimulatie en langere follow- up periode thuis waarbij contaminatiebias vanuit mogelijke contacten en delen van ervaring tussen controle- en interventiekinderen nog beter gecontroleerd kunnen worden.

5

Annexes: questionnaires and forms

General Guidelines for data collectors

Sequences of the data collection

1. First, make sure that the respondent has signed consent form to participate in the study.
2. Then, to ensure that the child is eligible to participate in the study, evaluate him/her against the following points summarized in table below.

A. Exclusion criteria for benchmarking group

S.No	Points of reference	Yes	No
1.	Was the body size of the child (when you judge him or her in terms of categories such as very large, larger than average, average, below average, very small/tiny, and extremely very tiny/small) very tiny at birth?		
2.	Was the child below a normal birth weight (less than 2 kilograms) at delivery?		
3.	Was the child born as a twin/ triplet?		
4	Was the child born being pulled out by instrument/forceps?		
5.	Was the mother under a severe and prolonged labour of more than 24 hours during delivery of the child?		
6.	Does the child have visible impairments affecting sight or/and hearing, or/and mobility?		
7.	Does the child have a chronic health problem and is always sick?		
8	Did the mother have **very serious health problems during pregnancy** while the child was in womb?		
9.	Was the child born more than 2 weeks before the expected date of birth as premature baby?		
10.	Is the child (has he been) **frequently** sick during the first year of life?		

B. Criteria for excluding SAM children from psychomotor/psychosocial stimulation study

S.No	Points of reference	Yes	NO
1.	Does the SAM child come from outside of 45 kilometre radius from Jimma town?		
2.	Does the SAM child have congenital abnormalities such as deformity, spinal bifida, paralysis on the limbs that hinder play therapy?		
3.	Is the SAM child completely deaf and/or blind?		
4.	Does the caregiver of the SAM child have mental or physical disability to follow up the child?		

3. If you find that the child satisfies the abovementioned lists and that the care giver has reported YES to any of the points of assessment, then drop the child from the study.
4. If two children are enrolled from the same family, concerning the second child, jump on questions 1-16, and ask only questions 17-26. Give the same code for the caregiver, but a different code for two children of the same caregiver. Use the same folder for both caregiver and children of the same family. While you complete the questionnaire with caregiver, considering the age of the child, provide Denver materials such as ball or doll to familiarize the child with it. But carefully follow up what the child does with it, and take care of damage or loss.
5. As soon as you finish completing the questionnaire for the caregiver, proceed to measure MUAC, height and weight of the child respectively.
6. As soon as you finish completing the questionnaire for the caregiver, proceed to measure MUAC, height and weight of the child respectively.
7. Finally, proceed to Denver II-Jimma testing after weight is measured.

Consent to be made by a caregiver(mother, father or closer guardian)
Introduction:

Parents wish all the best for their children, and a nation's hope for its future is inconceivable without the children of today. Hence, children have to be studied and understood to help them grow and develop well.

Dear caregiver (mother/guardian):

As part of the partnership cooperation between Jimma University and group of universities in Belgium, we are conducting investigation on how children interact with people and play with objects in their daily life. Our focus is on children of 6 months through five years of age. We provide them some play objects and see how they manipulate the objects under the instruction of a trained person and in the presence of you the caregiver. In order to get certain information about the child, a caregiver/mother familiar with the child is needed. Hence we kindly request you to cooperate with us in allowing us to involve your child in our study by availing yourself during the 20-30 minutes of the play session with your child, and by providing some information about the child. The study provides information on how children develop, and helps to design appropriate program that parents and organizations working on children can use to enhance healthy growth & development of children.

We assure you that there is no any harm on you and your child for taking part in this study. Yet, you and your child have the full right not to participate in this study if you do not want. Your cooperation, on the other hand, contributes much in providing information that would be used for the betterment of life of children.

If you agree to cooperate, please put your name and signature on the space provided on the paper attached herewith.

Thank you for your cooperation
The study team leader
Jimma University

Child Psychomotor/Psychosocial Stimulation Study Consent Form

I , the undersigned, understand that the purpose of this study is to take some measurements of my child. I am aware that these measurements will enable us to acquire information about the physical shapes of children at different age levels and to use this information in constructing guidelines for the safer design of children's products.

I have been informed that there will be no health hazards or discomfort to my child associated with this, and that participation is voluntary. In order to take measurements with accuracy, it is necessary for the child to partially undress**,** leaving on his/her underwear. Each child is measured individually, and all steps are taken to insure privacy.

I further understand that all of the data is confidential and I agree to allow publication of any or all of the data collected on my child if presented in a coded form.

Child's Name ______________________________ Signature of Parent ________________________

Boca Waliigaltee Qo'annoo Saayikoomootorii Daa'immanii

Ani, maqaa fi mallattoonkoo gadditti kan argamu, qo'annooni kuni mucaankoo umuriisaatiin wantanni hojjechuu danda'u baruudhaaf hojjaa fi ulfaatina isaa/ishee dabalee haala taphaatiin wantoota inni/isheen raawwachuu danda'u/dandeessu safaruuf akka ta'e nan hubadha. Safara kana gaggeessuudhaan odeeffannoo maatiin, ogeessotni fayyaa fi barsiisotni itti fayyadamanii tajaajila barbaachisaa ta'e haala umurii daa'immannii ilaalcha keessa galcheen kennaniif kan gargaaru ta'uu isaa nan hubadha. Safara kana geggeessuun fayyummaa mucaakoorratti dhiibbaa tokko akka hinqabne fi qooda fudhachuun dirqama tokko malee ta'uunsaas naaf ibsameera. Dogoggora safarrii hanbisuuf jecha wantootni akka kophee fi uffata ulfaatoo ta'an irraa baasuudhaan uffata keessaa qofaan safari geggeeffamu akka qabus nan amana. Safarri kun bakka ani jirutti akka geggeeffamu fi odeeffannoon argamu hiccitiin kan eegamu akka ta'e kan naaf ibsame yammuu ta'u, haala maqaa mucaakootii hin ibsineen mallattoo/koodii fayyadamuudhaan odeeffannoo funaanamu maxxansiisuun akka danda'amu eyyammeera.

________________ _______________ ________________

Maqaa Mucichaa Mallattoo abbaa/haadhaa Guyyaaa

Waliigaltee/eeyyama Maatii

Kabajamoo haadha/abbaa ____,

Yuunivarsiitiin Jimmaa qorannoowwan rakkoolee hawaasaa gidugaleessa godhatan gaggeessaa jira. Kana keessa qorannoon dagaagina daa'immanniirratti godhamu isa tokko dha. Qorannichi ijoolleen hanqina albuuda nyaanta keessaan hubaman umurii saaniin walqabatee wantoota isaan raawwachuu danda'an adda baasanii baruudhaan deggarsa umuriisaaniin madaalame kennufiif jecha kan gaggeeffamu yammuu ta'u argannoon qorannichaa odeeffannoo barbaachisoo ogeessota fayyaaf, maatiidhaafi barsiisotaaf kennuuf ni gargaara.

Qorannoo kana keessatti kan qooda fudhatan daa'imman hubama albuuda nyaataa qaban umuriin isaanii ji'a/baatii 6 hanga wagaa 5 ta'an fi guddiftuu isaanii waan ta'eef qorannoo kanaaf isiniifi mucaankeessan filatamtaniittu. Kanaaf jecha, akka isin nu atoomtan/eeyyamtan ulfinaan/kabajaan isin gaafanna.

Oddeeffannoon kan funaanamu mucaakeessanii wajjin yeroo isin asi Hoospitaala jirtan, gara mana keessaniitti deebi'uuf guyyaa tokkoon duraa fi erga manatti galtaniin booda gara mankeessanii kan dhufan dubartoota ogeessota fayyaa /neersota ta'aniin. Odeeffannoo argachuuf ***wanti yaaliidhaaf jedhamee mucaarraa fudhamu (FKN, dhiigni, booliin) tokkollee kan hin jirre yammuu*** ta'u mucaan umurii isaatiin/isheetiin maal akka raawwachuu danda'u/danddeessu beekuudhaaf haala taphaatiin wantoota raawwataman itti kennuudhaan, isiniin gaafachuudhaan, daawwachuudhaan, hojaa fi ulfina isaa/ishee safaruudhaan ta'a.

Odeeffannoon funaanamu aanaalee Godina Jimmaa jalattii argaman keessaa waan ta'eef dura bu'uun haala teessoo namoota qorannoo kana keessatti qooda fudhatanii baruun gara manaa deemanii jaraa quunnamuuf barbaachisaadha. Kanaaf jecha, yoo qorannoo kana keessatti qooda fudhachuun odeeffannoo nuuf kennuuf hayyamtan bakka duwwaa gaditti argamurratti maqaa mucaakeessanii, guyyaa dhalootaa, maqaa keessanii fi mallattoo keessan barreessuudhaan akka nuuf mirkaneessitan kabajaan isin gaafanna.

<u>**Maqaa mucaaa**</u> <u>**Saala**</u> <u>**Guyyaa dhalootaa**</u>

______________________________ ________ Guyyaa____ Ji'a_____ Bara_______

Bakka Jireenyaa: Godina Jimmaa, ***Aanaa***______________ ***Ganda***___________________

Zoonii_________________***Garee***___________***Gooxii***____________***Lakk. manaa***___________

Lakk. Bilbilaa /Moobaayilaa____________________

Maqaa addaa bakkichi ittiin beekamu/ mallattoo addaa____________________________

Buufata fayyaa/kiliinika naannookeessanitti/ dhiyootti argamu________________________

Maaqaa _________________ Mallattooo__________ Guyyaaa_______________________

Boca Waliigaltee Qo'annoo Saayikoomootorii Daa'immanii-----2

Ani, maqaa fi mallattoonkoo gadditti kan argamu, qo'annooni kuni mucaankoo umuriisaatiin tapha inni/isheen taphachuu danda'u/dandeessu fayyadamanii dadamaqsuudhaan jijjiirraa inni guddina fi dagaagina isaa/ishee irratti fidu qo'achuuf akka ta'e hubadheera. Kanaaf jecha Hoospitaala Jimmaa keessatti hogeessota fayyaa dhimma kanaaf leenji'an waliin ta'ee haala mucaa itti taphachiisuudhaan dadamaqsan hordofee gara manaattis yammuun deebi'u itti fufuuf, si'a sadii manakoo dhufanii hordoffii godhanii haala ani itti mucaakoo taphachiisu akka na agarsiisanis eeyyamee fedhakootiin qo'annoo kana keessatti mucaakoo wajjin hirmaachuuf murteesseera. Jijjirraa argame safaruudhaaf jecha haala taphaatiin dagaagina mucichaa akka safaran, hojjaa/dhaabbii isaas fi ulfaatina isaas akka safaraniif eyyameera. Safara kana geggeessuun fayyummaa mucaakoorratti dhiibbaa tokko akka hinqabne fi qooda fudhachuun dirqama tokko malee ta'uusaaf qoannoo kanaan walqabatee kaffaltiin tokkoyyuu akka naaf hinkennamnes, yeroon fedhetti qo'annicha addaan kutuun mirgakoo akka ta'es naaf ibsameera. Dogoggora safarrii hanbisuuf jecha wantootni akka kophee fi uffata ulfaatoo ta'an irraa baasuudhaan uffata keessaa qofaan safari geggeeffamu akka qabus nan amana. Safarri kun bakka ani jirutti akka geggeeffamu fi odeeffannoon argamu hiccitiin kan eegamu akka ta'e kan naaf ibsame yammuu ta'u, haala maqaa mucaakootii hin ibsineen mallattoo/koodii fayyadamuudhaan odeeffannoo funaanamu maxxansiisuun akka danda'amu eyyammeera.

<u>Maqaa mucaaa</u> **<u>Saala</u>** **<u>Guyyaa dhalootaa</u>**

__________________ _______ Guyyaa______Ji'a________Bara______ Bakka Jireenyaa: Godina Jimmaa, Aanaa___________ Ganda________________

Zoonii______________Garee________ Gooxii___________ Lakk. manaa______

Lakk. Bilbilaa /Moobaayilaa _____ Maqaa addaa bakkichi ittiin beekamu ykn mallattoo addaa____

Buufata fayyaa/kiliinika naannookeessanitti/ dhiyootti argamu_________________

<u>Maqaa Guddiftuu</u> <u>Mallattoo guddifitu/guddisaaa</u> <u>Guyyaaa</u>

_____________________ __________________ _________________

Annex: Home follow-up questionnare

Questionnaires completed during home visit

Name of caregiver/respondent: _______________________

Relationship with the child___________________________

Visit round: Underline one of these (1st, 2nd 3rd)

Name of child: __________________ Sex: _______ Age: ______

Yeroo daawwanaan manaa godhamu haala dadamaqiinsaa guddina daa'immanii dagaagsuuf

1.	questions	Indicate by putting "**X**" mark			
2.	Has the child been following the intervention continually?	Yes	No		
3.	With whom has the child been playing more often?	alone	Other children	Adults in the family	
4.	Has the child been interested in attending the play sessions?	Yes	No		
5.	How often has the child been getting guided play <u>each day</u>?	once	twice	Trice or more	
6.	How often do family members other than the trained caregivers take part in stimulation of the child?	sometimes	always	rarely	
7.	Was the child sick after discharge from the hospital?	Yes	No		
8.	Did the child stop the stimulation/play because of sickness?	Yes	No		
9.	If yes, for how many days did he stop?______days				
10.	Where often was the child engaged in play activities?	At home	neighbour	on bed	
11.	How often does the trained caregiver engage the child in play?	sometimes	always	rarely	
12.	Has the child been getting plumpy nut (BP 100) from nearby health centre **after discharge from the hospital/last home visit**?	sometimes	always	rarely	Not at all
13.	If "rarely" or "not at all", what does your child get?	specially prepared home food	Whatsoever is available for family	Cow milk	Powder ed milk or 'Nido'
14.	After **discharge from hospital/last home visit**, how often was the child taken to nearby health centre for follow up?	**once**	**twice**	Trice and more	Not taken at all
15.	What are the major challenges faced so far in working on the child?				
16.	What do you think should be done to make the child support more effective/interesting?				
17.	What did you like most so far while working with the child?				
18.	What is your overall comments/suggestions on what is being done to your child?				
19.	Brief description of the nature of the home environment for the SAM child stimulation				

qodhamaa jiru ilaalchisee gaaffileewwan guddiftuun gafataman.

Guyyaa daawwanaa manaa: ________________Daawwattoota: ________________________

Marsaa daawwanaa: **(**1^{ffaa}, 2^{ffaa}, 3^{ffaa})

Maqaa mucaa:______________________ Saala________ Umurii:_________________

Maqaa guddiftuu:_______________ Mucaadhaaf malsaati/maalsheeti?_______________

Annex: questionnaire to document information at baseline and end-line

ASQ:SE Age Category __________ Name of Data Collector________________________________

Name of child____________Date of birth_________Sex_______ Child Code___________________

Date of today: ------------------------------- Code for respondent/caregiver ---------------------

1. Name of respondent---Relationship with the child (mother, father, grandmother, grandfather, foster mother, employed caregiver)

   Residential address: Woreda/district -----------------------------------Kebele--------------------------------Garee--------------------
   Gooti: -------------------- House Number---------------- Special name of the place: ------------------------------------

		A	B	C	D	E	F.	G	H
2	Age of mother----------	less than 20 yr ☐	20-30 ¯yr. ☐	31-40 yr. ☐	*above 41 yrs.* ☐				
3	Mother's religion	Islam ☐	Orthodox Christian ☐	protestant christian ☐	traditional religion ☐	Catholic ☐	other ☐		
4	Father's religion	Islam ☐	Orthodox Christian ☐	protestant christian ☐	traditional religion ☐	Catholic ☐	other ☐		
5	Education level of mother	illiterate ☐	grade 1-8 ☐	grade 9-12 ☐	certificate ☐	diploma ☐	degree & above ☐		
6	Education level of father	illiterate ☐	grade 1-8 ☐	grade 9-12 ☐	certificate ☐	diploma ☐	degree & above ☐		
7	Marital status of Mother	husbanded ☐	divorced ☐	widow ☐					
8	Occupation of mother -----------------------	house wife ☐	teacher ☐	office worker ☐	health professional ☐	Field work ☐	Tradition al farm ☐	Trade ☐	other ☐
9	Occupation of Father ---------------------	daily laborer ☐	teacher ☐	office worker ☐	health professional ☐	Field work ☐	Tradition al farm ☐	Trade ☐	other ☐
10	Ethnicity of Mother	Oromo ☐ Amhara ☐	Tigre ☐ Gurage ☐	Silte ☐	Dawuro ☐	Yem ☐	Keficho ☐	Welayita ☐	other ☐
11	Ethnicity of Father -----------------------	Oromo ☐ Amhara ☐	Tigre ☐ Gurage ☐	Silte ☐	Dawuro ☐	Yem ☐	Keficho ☐	Welayita ☐	other ☐
12	Monthly income of mother and father	less than 500 birr ☐	500-1500 birr ☐	1501-3500 birr ☐	above 3500 ☐				
13	Family socio-economic status (perceived by respondent	higher ☐	middle ☐	low ☐	very much lower ☐				
14	Residential address	town/urban ☐	suburban area ☐	small village ☐	rural				

15	Household furniture possessed (More than one is possible to choose)	pipe water ☐	electricity ☐	Local TV station receiver ☐	sattellite TV receiver ☐	radio ☐	DVD deck ☐		
16	Type of house of the family	private, made of mud ☐	Private, made of cement ☐	rented, made of mud ☐	Rented, made of cement ☐	Governme nt ☐			
17	*Birth order of the child*	*first born* ☐	*2nd born* ☐	*3rd born* ☐	*between 3rd and last born child* ☐	*last born* ☐			
18	*Schooling of the child*	*not started schooling* ☐	*nursery* ☐	*KG1* ☐	*KG2* ☐	*KG3* ☐			
19	*Number of persons living under the same roof with the child*	*less than 3* ☐	*3-6* ☐	*7-10* ☐	*above 10* ☐				
20	*Number of children the child meets in neighbour*	*less than 3* ☐	*3-6* ☐	*7-10* ☐	*above 10* ☐				
21	*Frequency of the child's interaction with other children*	*always* ☐	*sometimes* ☐	*never interacts with others* ☐					
22	*Mother-child interaction time*	*during feeding and toileting* ☐	*out of working hours* ☐	*always together* ☐					
23	*A person more often attached with the child*	*elder brother/ sister* ☐	*younger brother/sister* ☐	*a child less than 11 years of age* ☐	*grandparents* ☐	*the child is lonely* ☐			
24	*Facilities for play*	*has different play materials* ☐	*has play corner arranged for him* ☐ ☐	*plays cultural dances, songs and riddles with family* ☐					
25	*Time spent on play by the child*	*Always* ☐	*sometimes* ☐	*very rarely* ☐	*does not play at all* ☐				
26	*Child feeding condition*	*gets age appropriate diets* ☐	*gets what is available for family* ☐	*has very poor appetite for food* ☐	*does not get sufficient food* ☐				

Guyyaa hari’aa______________Koodii nama odeeffannoo kennee____________Koodii mucaa________
Maqaa nama odeeffannoo kennuu _____________Mucaa dhaaf maliidha? (haadha, abbaa, akkoo, akaakayyuu, guddiftuu ykn haadha biddeenaa, guddisaaf nama qacarame)
Bakka jireenyaa: Aanaa______________Ganda_______________Garee_____________Gooxii________Lakk. manaa_________________Bilbila ________________ Bakki jireenyaa keessan maqaan addaa ittiin beekamu___________________________________

Lak.		A	B	C	D	E	F.	G	H
1.	Umurii haadhaa mucaa	waggaa 20 gadi ☐	wagaa 20-30 ☐	wagaa 31-40 ☐	wagaa 41 oli ☐				
2.	Amantii haadha mucaa	Islaama ☐	Kirstaana ortodoksii ☐	Kiristaana proteestaantii ☐	amantii aadaa ☐	Kaatolikii ☐	kaan biraa ☐		
3.	Amantii abbaa mucaa	Islaama ☐	Kirstaana ortodoksii ☐	Kiristaana proteestaantii ☐	amantii aadaa ☐	Kaatolikii ☐	Kan biraa ☐		
4.	Sadarkaa barumasa haadhaa	dubbisuu fi barreessuu hin dandeenye ☐	kutaa 1-8tii ☐	kutaa 9-12tii ☐	seertifikeeta ☐	diploomaa ☐	digrii fi isaa oli ☐		
5.	Sadarkaa barumsa abbaa	dubbisuu fi barreessuu hin dandeenye ☐	kutaa 1-8tii ☐	kutaa 9-12tii ☐	seertifikeeta ☐	diploomaa ☐	digrii fi isaa oli ☐		
6.	Haala heeruma haadhaa	abbaa manaa wajjin jirti ☐	kan hiikte ☐	abbaan manaa kan irraa du’e ☐					
7.	Hojii haadhaa	haadha warraa ☐	barsiiftuu ☐	hojjettuu biiroo ☐	hogeettii fayyaa ☐	Hojii diree ☐	qonnaa aadaa ☐	daldaala ☐	kan biraa ☐
8.	Hojii abbaa	hojii guyyaa ☐	barsiisaa ☐	hojjetaa biiroo ☐	ogeessa fayyaa ☐	Hojii dirree ☐	qonnaa aadaa ☐	daldaala ☐	kan biraa ☐
9.	Sabummaa haadhaa	Oromoo ☐	Amaara ☐	Tigiree ☐	Guraagee ☐	Daawuroo ☐	Kafichoo ☐	Walaayitaa ☐	Kan biraa ☐
10.	Sabummaa aabbaa	Oromoo ☐	Amaara ☐	Tigiree ☐	Guraagee ☐	Daawuroo ☐	Kafichoo ☐	Walaayitaa ☐	Kan biraa ☐
11.	Galii ji’atti haadaa fi abbaan argatan	Birrii 500 gadi ☐	Birrii 500-1500 ☐	Birrii 1500-3500 ☐	Birrii 3500 oli ☐				
12.	Sadarkaa dinagdee maatii keessanii (kan isinitti fakkaatu)	ol aanaa ☐	giddugaleessa ☐	gad aanaa ☐	baayyee gad aanaa ☐				
13.	Bakki jireenyaa keessan	magaalaa ☐	naannoo magalaa ☐	mandara bicuu ☐	baadiyyaa ☐				

14.	tajaajila mana keessaa qabdan (2 ol filachuu dandeessu)	Bishaan ujummoo /boonbaa ☐	tajaajila humna elektrikaa ☐	tamsa'ina TV biyya keessaa ☐	TV saatelaayitii ykn diishii ☐	raadiyoo ☐	deekii vidiyoo ☐		
15.	Haala mana jireenyaa	kan dhuunfaa ta'ee dhoqqeedhaan kan maragame ☐	kan dhuunfaa ta'ee simiintoodhaan kan ijaarame ☐	kan kireeffame ta'ee dhoqqeedhaan kan maragame ☐	kan kireeffame ta'ee simintoodhaan kan ijaarame ☐				
17	**Tartiibni dhaloota mucaa kanaa isa kami?**	**hangafa** ☐	**2ffaa irratti dhalate** ☐	**3^{ffaa} irratti dhalatee** ☐	**3^{ffaa} fi isa dhummaa gidduu** ☐	**isa dhumaa** ☐			
18	**Haala barumsa mucichaa**	**barnoota hin jalqabne** ☐	**neersarii** ☐	**K.G 1^{ffaa}** ☐	**K.G 2^{ffaa}** ☐	**K.G 3ffaa** ☐			
19	**Baayina namoota mucaa kanaa wajjin mana tokko keessa jiraatanii**	**3 gadi** ☐	**3-6** ☐	**7-10** ☐	**10 oli** ☐				
20	**Baayina ijoollee mucichi ol'aatti ittiin walarguu**	**3 gadi** ☐	**3-6** ☐	**7-10** ☐	**10 oli** ☐				
21	**Mucaan kun ijoollee biraan kan walargee taphatu**	**yeroo danuu** ☐	**darbee darbeeti** ☐	**tasuma wal hin argu** ☐					
22	**Yeroo mucaan kun haadha argu**	**yeroo dhiqanif nyachisani** ☐	**yeroo hojiin ala qofa** ☐	**yeroo hunda walumaan** ☐					
23	**Mucichaa wajjin yeroo danuu kan dabarsu**	**obbolaa hanafa ta'an** ☐	**obbolaa quxisuu ta'an** ☐	**mucaa waggaa 11 gadii** ☐	**akkoo ykn akaakayyuu isaa** ☐	**qofaa isaa dabarsa** ☐			
24	**Taphaaf haalli mucichaaf mijatee jiru**	**meeshaalee taphaa adda addaa qaba** ☐	**bakka taphaaf qophaa'eef qaba** ☐	**tapha akka sirbaa, faarsaa fi hibboo** ☐					
25	**Mucichi yeroo inni taphaan dabarsu**	**yeroo danuu** ☐	**darbee darbee** ☐	**yeroo muraasa** ☐	**tasuma hin taphatu** ☐				
26	**Haala nyaataa/ soorata mucichaa**	**nyaata umuriisaatiif ta'u** ☐	**nyaatuma maatiin argatu qofa** ☐	**fedhiin nyaataa mucichaa bicuudha** ☐	**nyaata ga'aa hin argatu** ☐				

Description of the qualitative approach used in the adaptation process of the Denver II into Denver-II Jimma

Identification of a tool suitable to the study subjects and context started through literature search. Tools that have been used in assessing developmental outcomes in children have been targeted. Diagnostic and screening tools that have been developed in the Western industrialised nations and used for assessing developmental outcomes in children in low and middle income countries have been identified, examined and selected. For selection, attention was given to the feasibility of using the tools in the study context on the severely acutely malnourished children. Key selection criteria included cost of the tool, the expertise needed to administer it (not requiring specialized training and professionals), ease of administration and quick assessment (which makes it suitable to use on weak and fragile children), feasibility to use it in any setting (home, hospital, health centres, kindergartens) and on children from birth to six years. The tools more appropriate according to the selection criteria were chosen at a meeting among the study team comprising different professionals: paediatricians, neuro-scientist, nutritionists, a nurse and counselling psychologist, an educational psychologist and play therapist, a teacher educator with special needs education training, a physiotherapist, a physiotherapist/ occupational therapist, and a child psychiatrist. Each of the test items in the selected tool was examined for being cross-cultural or culture-specific. The test items were categorized into culture-specific movement skills and cross-cultural non-movement skills. In doing so, resources such as International Classifications of Functioning and Disability (2007), *Movement Skills Assessment* (Burton and Miller, 1998) and Cross-cultural psychology: research and applications (Berry, Poortinga, Segall, & Dasen, 2002 were consulted. The test-items identified through literature search were further discussed at a joint consensus meeting held among the multidisciplinary study team: Ethiopians (local academic staff and practitioners familiar with the study setting and cultures) and Europeans (academicians and practitioners with Western culture). Test items identified as culture-specific were then translated into two local languages and piloted for feasibility on a small sample (N=19) of urban and rural households. After analysis of the pilot survey, a consensus meeting was held among the study team, and items (N=36) that needed adaptation were identified, modified, translated for piloting on small sample (N=8) (Draft I version). Then, two members of the European study team trained three local team members on the administration and scoring of the original tool using the manual and a video prepared by the original tool developers. Meanwhile, discussions addressed the administration and scoring of items identified and modified through pilot survey and subsequent consensus meeting. After practical training, a local study team (a nurse and psychologist, a psychologist and a special educator) piloted the tool to examine feasibility on a small sample (N=10) of kindergarten children while the two European trainers supervised the process. A subsequent meeting evaluated the feasibility of the test items, fine-tuned the adaptation of some items and suggested improvement in item administration procedures (Draft II version). Kindergarten teachers were identified and trained as testers to administer the Draft II version. The main aim was to examine the reliability of the adapted tool. The testers worked in pairs and administered the test on kindergarten children (N=24). Each tester independently took note (for further assessment of feasibility) to document challenges encountered while administering each test item, and reported at a meeting held after the data collection. Based on the input obtained, further modifications resulted in Draft III version. Following the adaptation process on small samples, a quantitative approach was used to standardize each test item and determine its reliability on a large sample (N= 1597). Data collection and analysis at this stage also included a qualitative approach: testers regularly reported challenges observed in administering each test item informally every day and formally at a weekly meeting; a consensus meeting was held among multi-disciplinary study team following the quantitative data analysis and reporting. The following table summarizes the steps followed and activities accomplished in the adaptation and standardization process of Denver-II into Denver II-Jimma.

Annex: *Breif summary of the steps followed in the adaptation process of the Denevr II into Denver II-Jimma*

The steps in the adaptation and standardization process of the Denver II into Denver II-Jimma

Study steps, methods and major outcomes	**Literature study**	**Exploratory survey**	**Exploratory tryout of feasibility**	**Exploratory tryout of reliability**	**Standardization study**	**Final Consensus**
	Main outcome: - 55 Items identified through cultural labeling as culture dependent	Main outcome: - 36 of the 55 items needed adaptation (19 test items were found to be culture fair (didn't need adaptation) - Resulted in Draft I	Main outcome: 38 adapted items - 1 new item added; - 8 items were found difficult to perform: 2 adapted, & 6 re-adapted) - Resulted in Draft II	Main outcome: 36 adapted items - 4 PS items with unacceptable kappa values; - 1 item newly adapted - Adaptation of 3 LA items dropped; - 2PS item re-adapted;	Main outcome: Final 36 adapted and one newly added items of the Denver II-Jimma Draft III	Main outcome: 36 adapted items Denver II-Jimma (Final version)
Personal-social domain 26 test items	*Work for toy* *Feed self (R)* *Play pat-a-cake (R)* *Wave bye-bye (R)* *Play ball with examiner* *Imitate (household) activities (R)* *Drink from cup (R)* *Help in house (R)* *Use spoon/fork (R)* *Remove garment (R)* *Feed doll* *Put on clothing (R)* *Brush teeth with help (R)* *Wash and dry hands (R)* *Name friend* *Put on T-shirt (R)* *Dress, no help (R)* *Play board/card games (R)* *Brush teeth, no help (R)* *Prepare cereal (R)*	*Work for toy* *Feed self (R)* *Play pat-a-cake (R)* *Wave bye-bye (R)* *Imitate (household) activities (R)* *Drink from cup (R)* *Help in house (R)* *Use spoon/fork (R)* *Remove garment (R)* *Feed doll* *Put on clothing (R)* *Brush teeth with help (R)* *Wash and dry hands (R)* *Put on T-shirt (R)* *Dress, no help (R)* *Play board/card games (R)* *Brush teeth, no help (R)* *Prepare cereal (R)*	**New item added:** "Toilet going" This test item was added as a complementary task for the test item "prepare breakfast" **Item re-adapted**: "Feed doll" The task of feeding a doll was first changed by avoiding the use of a white baby doll for administering the item. It was replaced by the instruction "feed Daddy or Mammy". Re-adaptation was made by replacing the doll used to administer the test item from white baby doll to a dark /chocolate colored doll. "Prepare cereal " initially adapted as "Prepare breakfast" is re-adapted as "Serve oneself Injera"	Items with unacceptable kappa values and thus: **(a) adapted** "Name friend" into "name playmate" **(b) re-adapted** "Brush teeth with help" into "wash mouth" "Wash and dry hands" into "wash hands properly" **(c) pended adaptation** "Go to toilet" adaptation pended until tried on large sample. **Other re-adapted item** "Feed doll" The use of either of a white doll or a black/chocolate color doll other than feeding Mammy or Daddy as adapted initially.	*Work for toy* *Feed self (R)* *Play clapping game (R)* *Say or Wave bye-bye (R)* *Imitate (household) activities (R)* *Drink from cup (R)* *Use finger or Use spoon/fork (R)* *Remove garment (R)* *Feed doll* *Put on clothing (R)* *Brush teeth with help (R)* *Wash and dry hands (R)* *Name friend* *Put on T-shirt (R)* *Dress, no help (R)* *Play board/card games (R)* *Brush teeth, no help (R)* *Prepare cereal (R)* "Toilet going"	Adaptation of the item "work for toy" cancelled The newly added item "toilet-going" is dropped

Annex: Breif summary of the steps followed in the adaptation process of the Denevr II into Denver II-Jimma

Fine motor-adaptive domain 29 test items	*Follow to midline* *Follow past midline* *Follow 180°* *Regard raisin* *Reaches* *Look for yarn* *Rake raisin* *Thumb-finger grasp* *Put block in cup* *Scribbles* *Dump raisin, demonstrated* *Imitate vertical line* *Copy ○* *Draw person – 3 parts, 6 parts* *Copy +* *Copy □* *Copy □ demonstrated*	*Regard raisin* *Rake raisin* *Thumb-finger grasp* *Scribbles* *Dump raisin, demonstrated* *Copy ○* *Draw person – 3 parts, 6 parts* *Copy +* *Copy □*			*Regard coffee bean* *Rake coffee bean* *Thumb-finger grasp* *Scribbles* *Dump coffee bean, demonstrated* *Copy ○* *Draw person – 3 parts, 6 parts* *Copy +* *Copy □*	
Language domain 39 test items	*Turn to rattling sound* *Point to pictures – 2,4* *Name pictures – 1,4* *Body parts - 6* *Known actions – 2,4* *Name colors – 1,4* *Use of objects – 2,3* *Define words – 5,7* *Opposities – 2*	*Name pictures – 1,4* *Body parts - 6* *Use of objects – 2,3* *Define words – 5,7* *Opposites–2*	**Item adapted**: Name colors—1, 4** **Item re-adapted**: "Name pictures—1,4"* "Define words—5, 7" *the pictures for administering these items were difficult for some children to understand. It was suggested that colored photos of the pictures be used. ** the colors green and blue were difficult for children to name and thus recommended to be adapted.	***Adaptation dropped*** *"Body parts—6"* *Adaptation made to administer this item by using child's own body parts was dropped because children can use body parts of doll of their own colour choice.* *"Name 1 picture"* *"Name 4 pictures"* *Adaptation of these items(the use of photographs other than pictures) was dropped since children were able to understand the pictures.*	*Body parts—6* *Name colors – 1,4* *Use of objects – 2,3* *Define words – 5,7* *Opposites – 2*	
Gross motor domain	*Kick ball forward* *Throw ball overhand*	No adaptation or addition	No adaptation or addition	No adaptation or addition	No adaptation or addition	"Walk up-steps" adapted

Curriculum vitae

Teklu Gemechu Abessa graduated in 1992 with a bachelor degree in pedagogical sciences from Addis Ababa University, Ethiopia. He worked as a high school teacher for three years, and then joined Jimma Teachers' College where he got a Finnish International Development Agency (FINIDA) sponsored sandwich Masters Level study in which he obtained a Masters of Special Education degree from Joensuu University of Finland in 1998.

After serving for 2-and-a-half years at Jimma Comprehensive Secondary School, he re-joined Jimma Teachers College and worked there until 2004 as a lecturer, and a public and external relations officer, a national team member who developed a module of Higher Diploma Program for Teacher Educators working at colleges and universities in Ethiopia. In 2005, he joined a private Primary School Teacher Education Training Institute where he served as a dean. On 14 June 2005, he was employed at Jimma University and began serving as a lecturer at the department of psychology, and as a Leader of Higher Diploma Program for teacher educators. In 2006, he became a dean of a newly organized Faculty of Humanities and Social Sciences and served until February 2010. In a sandwich PhD program Teklu started a PhD in 2011 at the Faculty of Medicine and Life Sciences in REVAL Research Institute, Rehabilitation Sciences and Physiotherapy under the supervision of Prof. Dr. Marita Granitzer. He serves as a lecturer at the Department of Special Needs and Inclusive Education at Jimma University, Ethiopia.

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