CHAPTER III
RESEARCH METHODOLOGY

This Chapter described methods that were used to obtain results presented in the next Chapter. The methods started with the common issues which described the PCTC design. Then the methods were described separately for the two study aims-one for Aim 1 which involved children's preference for toy, and another was for Aim 2 which investigated the association between type of play materials and children's cognitive development.

3.1 Population and sample

The PCTC aims to generalize knowledge found in the sample to all Thai children. In this thesis, therefore, the population is all Thai infants aged of 1 year.

The sample of this thesis is all PCTC cohort members. There are 4,245 infants. These children were born to all women who had gestational age between 28th and 38th weeks and willing to participate in the study. Exclusion criteria were pregnant women who were abortion and could not communicate. There were 4,221 live births, 32 deaths after birth within 1 year and 11 withdrawers.

Northern region (N): All children who were born between March 20, 2001 and March 19, 2002 in Muang District, Nan Province.

Northeastern region (NE): All children who were born between January 20, 2001 and January 19, 2002 in Kranuan District, Khon Kaen Province.

Central region (C): All children who were born between October 15, 2000 and October 14, 2001 in Panomtuan District, Kanchanaburi Province.

Bangkok Metropolitan (BKK): All children who were born between September 7, 2001 and September 6, 2002 in Ramathibodi University Hospital

Southern region (S): All children who were born between November 17, 2000 and November 16, 2001 in Thepa District, Songkhla Province.

3.2   Protection of human subjects

The PCTC project was approved by the National Ethics Committee of the Ministry of Public Health on 22 September 2000. This research used data from the database of the PCTC and did not do any experiment or directly collected data from the sample. It reported over all data which could not link to individuals. Each subject had been given identification number by the project system. It could not link to the name, address or identity card. The thesis had been approved by the Khon Kaen University Ethics Committee for Human Research on 8 March 2010 (HE532078).

3.3   Instruments

For Aim 1 which involved children's preference for toy, the checklist or observation form (Appendix B4) and its manual (Appendix B3) had been used to record child play behaviors during 20-minute free play context. For Aim 2 which investigated the association between type of play materials and children's cognitive development, a case record form (Appendix B2) and its manual (Appendix B1) had been used to record number and type of toys at home. For this component of the study, cognitive development was assessed using the Capute scales.

Aim 1- Toy preference

The observation checklist of play behaviors for 15-20 minutes was used to collect the data regarding toy play behaviors. These include order of toy play, time of each play, and play behaviors for each toy. Twelve toys were placed on the floor in front of the infant. These, classified according to Chase (1994)[10] and grouped into 5 categories, include soft materials (i.e., soft human dolls and soft animal dolls), hard materials (i.e., wooden dolls), sound toys (i.e., squeeze sound toys, rattling sound toys, push button sound toys, and pounding sound toys), move to play (i.e., pull toys, walker or push along, throwing balls, and abacus toys), and literacy (i.e., pictorial books) (Appendix C).

Aim 2- Association between play materials and cognitive development

The case record form was used to collect the data regarding play materials in home environment and parent behaviors. Play materials were categorized according

to Chase [10]. By this, the researcher classified play materials into 12 types as well as counted them for each type. The 12 types of play materials include push/pull toys, home utensils, sound toys, junk materials, dolls and other soft toys, natural materials, story books, creative materials, writing materials, self-invented toys, stacking toys, and musical cassettes.

Cognitive development was using the Capute scale by the training pediatricians of the PCTC. This test has been used in Thailand [56, 57, 58].

3.4 Data collection procedure

Data collection of the PCTC was implemented under clear standard operating procedures (SOPs). The research assistants were trained according to the SOPs and were under close supervision by main researchers. Data regarding play materials were collected once children reached the age of 1 year (Figure 3.1)
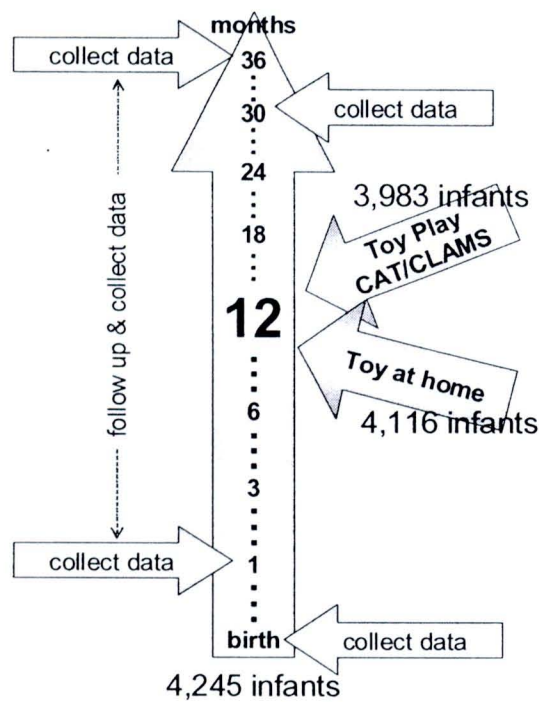

Figure 3.1 Design overview

The data collection forms were created by main researchers (Appendix D) who were specialists in this field. The research assistants were trained and randomly rechecked consistency; the monitoring and quality controls were established at the

beginning of the project to ensure reliability and validity. Data collection processes for each study aims were as follows.

Aim 1- Toy preference

Toy preference was collected in the play area at the hospitals that are the study site. At that occasion, there were 8 data collection forms being administered. These includes D07 to D14- infant toddler social emotional assessment, temperament assessment, caretaker's behavior, cognitive assessment, health examination, play behaviors, food consumptions and sleeping, and in-depth interview of child rearing. Play behaviors or D12 was an observation checklist for investigating toy preference.

In the hospital, they prepared a work area around 4×5 meters^2 for 5 parts (Figure 3.2): registry area, Capute scale and visual test area, Modified Infant Toddler Social Emotional Assessment (MITSEA) and temperament test area, play area (Figure 3.3), and physical examination area. The play area was nearby the MITSEA area which the parent would be asked for social emotional of their infant to make an infant ensure that he was not lonely. The area must be appropriate for the infant to play; no other stimulate thing except set of toys and a research assistant who recorded the data and did not allow to interact with the infant.

On the date that children visited the hospital according to the schedule visit, it was started by checking the process and cleaning the area. The area was cleaned by a hospital worker and also removed all the unnecessary or inappropriate things to make sure that the infant would not have any accident and the other stimulates. The process was verified by field manager which are included an appointment time, list of infant's and his parent's names, preparing of case record form, all instruments such as set of toy, and plan for solving any problem or an accident.

In the play area, 12 types of toys were arranged the way that children can equally reach if they wish to play. Play environments were arranged the same ways for all children. Their playing was observed by the assistants in a 20 minutes free-play context without interference of caregivers. The first toys being chosen to play by children were determined so that toys that are attention-getting can be identified. Duration of toy playing refers was used to determine toys' attention-holding. The assistant began to observe and record the data when she took an infant into the play area while the parent or caretaker was assessed the MITSEA.

Aim 2- Association between play materials and cognitive development

a) Variable of interest: Play materials

Data of play materials aged 1 year was collected by home visit. Six data collection forms were planned to collect at the same time. These were D01 to D06:- family economic structure and role of caretaker, child rearing, health care, family critic events, food consumptions and vaccination, and home environment and caretaker's behaviors. Play materials was part of the D06.

The visiting plan was scheduled by research assistants of each area and approved by head of the team in order to ensure the continuing process and appropriated time for each infant. The research assistants made an appointment with each parents accordingly. Also the main researchers were responsible for closely supervision at the first 2 days of each new process. This was set to solve the problem which was not guided in the data collection manual.

When the research assistant visited an infant's home, they explained the objectives of the visit and ask for permission for collecting the data. If an infant had more than 1 house, the data was collected only at the main house. But if S/he had no main house, the data was collected at all houses.

After walking around the house and recording home environment, the research assistant requested the main caretaker to bring play materials which were always played by the infants or took the infants to their play area that might have more than one place. The research assistant classified play materials into 12 types as mentioned previously and count the amount of play materials according to each type. The research assistant probed the questions to ensure that all play materials were identified. The research assistants are required to examine that the materials was really played by exploring that objects.

b) Outcome variable: Cognitive development

Cognitive development was measured 1 – 2 weeks after the home visit. That is, it was measured the same day the children visited the hospital at 1 year of age as mentioned in Aim 1. This is because Capute scale required to be administered by pediatricians. All pediatricians at each study hospital had experience using the tool- they had ever used the test for their previous study.
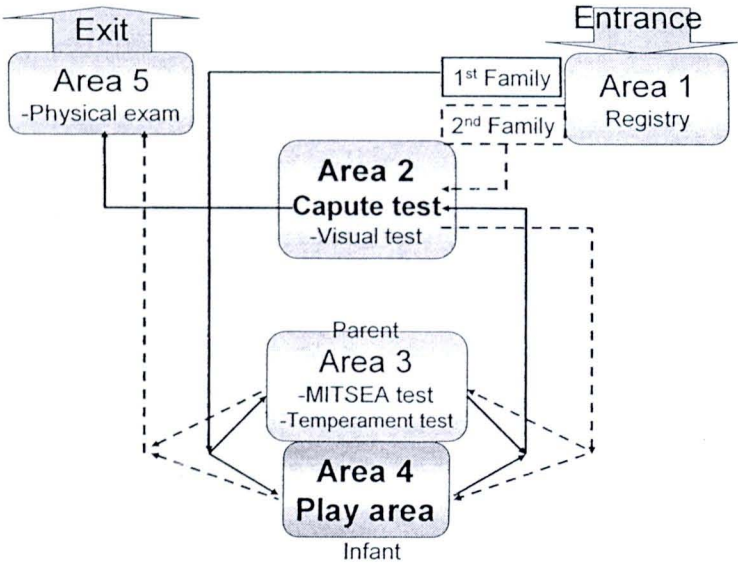
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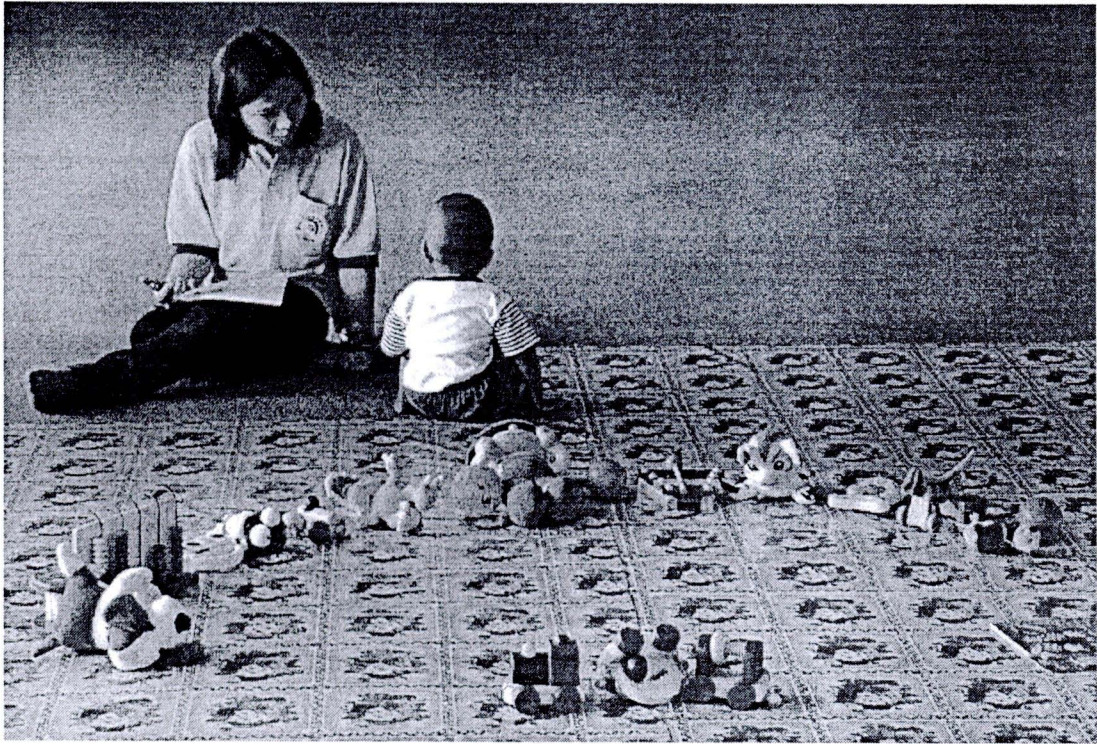**Figure 3.2** Work flow of toy preference component

Figure 3.3 The play area

3.5   Statistical methods

Demographic characteristics were described using mean and standard deviation for continuous variables and frequency and percentage for categorical variables. All analysis were done using Stata version 10 (StataCorp, College Station, TX). All statistical tests considered a probability of 0.05 as statistical significant level. Statistical methods for each study aims are as follows.

Aim 1- Toy preference

Attention-getting for each toy was quantified by percentage of children who choose the toy as the first one to play. Attention-holding for each toy was estimated by the mean of playing duration. The 95% confidence intervals (CI) were also calculated for each of these indicators.

Aim 2- Association between play materials and cognitive development

Play materials found in children's houses were listed with percentage of being played for each type, along with their 95% CI. Effects of play materials on Capute scale, being quantified by mean difference of the Capute scale comparing between children who played and who did not play the materials, were analyzed using simple linear regression. This serves as an exploratory effect of each type of the play materials without adjustment for effects of other factors. Univariate analysis for assessing effects of selected factors on Capute scale was also analyzed using simple linear regression. From this analysis, variables with p-value of less than 0.25 were included in the initial multiple regression model. Form the final multiple linear regression model, effect of each type of play materials on Capute scale was estimated. The magnitude of effect was presented as mean differences and their 95%CI which were adjusted for effects of other type of play materials, study center, parent's factors (i.e., age, education, marital status, and income), children's factors (i.e., sex, weight, height, gestational age, birth weight, breast fed, hospital admission, mother's attachment, number of member, number of sibling, iodine consumption and life events).