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The effect of developmental activities, embedded into parents activities of daily living, on supine sleeping infant milestone development

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CHAPTER 3 PROGRAMME DEVELOPMENT AND RESEARCH METHODOLOGY

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This study was divided into two parts.

Part A (represented in green in Figure 3.1) – to design and validate a programme to improve motor development of infants that could be incorporated into a mother's ADL.

Part B (represented in blue in Figure 3.1) – an experimental research study to establish the effect of the programme on motor development of infants who do not sleep in the prone position.



Figure 3.1 Flow diagram indicating the process of the study, indicating Part A (green) and Part B (blue)

Part A: Programme Development

The first part of this chapter will discuss the development of the postural control programme, the rationale for activity inclusion and the process of creating a photo sheet to provide visual prompts for mothers as they carried out the programme.

3.1 Programme design

The programme was designed using the understanding of normal development that has been summarised in the literature review and holding to the principles of family centred care. The theories surrounding the manner in which mothers construct their daily routines was referred to consistently in order for the programme to be sustainable. The programme was therefore designed around the premise that the activities used must be part of the normal tasks of the *mother* and a natural part of her interaction with her baby.[29, 34] It is therefore multi-systemic, and is intended to support a new mother who is making the transition to the roles and habits and occupational performance of 'motherhood'.[7, 84, 107]

A summary of what was considered 'optimal' for this age span was incorporated on the activity sheets created for the purposes of brainstorming activities. (Appendix A) Activities that could be useful to challenge prone positioning, were then brainstormed. This creative process considered any number of parenting tasks and whether a 'tummy time' activity/posture/movement could be inserted into it. Activities of daily living for most mothers in the early months of their infants' lives revolve around baby care such as bathing, feeding, consoling and interaction, household management such as cooking, cleaning, and laundry, and also extent to leisure, social and personal management pursuits which existed before the birth of the baby. Many of the activities/postures for mothers to do with their baby were

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adapted from activity ideas prescribed for developmentally delayed infants.[87, 108] Some ideas were inspired by the Motor Activities Programme of the PDMS-2,[109] others were from personal experience.

From this brainstorming process, a list of activity ideas that would form the basis of the Infant Postural Control Programme (IPCP) was created, with considerations for position, grading and uses. (Appendix A)

The underlying philosophy adopted during this process was to 'de-medicalise' the programme. The use of the mother's own body and everyday activities, combined with ideas that would resonate as common sense was deliberately used to enable the mother to own the process of stimulating her baby's growth.[84, 85]

3.2 Postural Control Programme Validation

3.2.1 *Content Validity*

3.2.1.1 Pilot study 1: Initial Activity Validation

Initial versions of the programme were sent, in written format with sketches of positions, to a panel of four experienced therapists to validate the content.

Panel selection

Two occupational therapists and two physiotherapists, all of whom have particular interest and many years experience in the treatment of infants and young children, were approached to participate in the initial pilot study.

Inclusion criteria

- 10 years experience the treatment of infants and young children,

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- and/or post-graduate qualification

in order to qualify as an expert for validation purposes.[110]

After the panel had had a chance to look at the initially proposed programme, an individual interview time was arranged and the therapists were able to comment on the activities.

At each interview, comments related to suitability, safety, appropriateness and applicability of the activities, were garnered. The therapists rejected structuring that they considered too specialized and those that they anticipated would be better taught in a one-to-one session by a therapist. Water play activities were discarded because of safety and liability factors. The therapists gave advice regarding grading of activities and often moved structuring to a later age or started a movement in a more controlled manner at an earlier age. Their input regarding key teaching points, facilitation techniques and ideas for activity progression was invaluable. Generally the advice given helped to simplify the task for parents. They also brought their experience to bear on how best to teach parents' various handling concepts.

A complete list of the original activities, including those which were discarded, and a compilation of the expert's comments is available as Appendix A.

Where the advice of the therapists was in conflict, the advice of the most experienced therapist was taken as the decisive authority.

3.2.1.2 Pilot study 2: Interim Activity Validation

Following the initial comments, a second draft of the activities, in written form, was sent to the panellists who were prepared to continue with the programme beyond the interview stage. The revised panel of experts consisted of one occupational therapist and one physiotherapist, who had previously assisted during the first

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iteration of content validation. Once the therapists had seen this final draft and approved the content, the programme design was finalized and the production of the photo-sheets, as well as the nurse's training manual was started.

3.3 Photo sheets

3.3.1 *Photo Sheet Design*

The process of creating meaningful, instructive photo-sheets that would accompany the training given by the nursing sisters was undertaken as part of the programme design. It was considered important for the photo sheets to be a simple reminder of the activities that the nurses had taught when the mothers returned home, and also provide a teaching tool for the nurses.

Verbal permission was obtained from each mother who participated in making the photographs, with her baby. It was made clear at the time that the purpose of the photo-sheets was for a research project. Should the programme be published in the future, written permission would be sought from the mothers to allow their photographs to continue to be used.

The photographs were taken with age appropriate infants known to the researcher. The infants were posed with their own mothers, in their homes, so that interaction and activity participation could be conveyed. (Figure 3.2) This was also a process of trying the activities with a 'lay person'. Each of the mothers photographed was taught the activity as the programme defined it and photographs were taken of the real-life execution of these activities.

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Figure 3.2 Pushing up on arms and reaching in natural play

The photo-sheet layouts were compiled in conjunction with a graphic designer. The intention behind the designs was for them to be fun and not at all prescriptive – rather to give a variety of postural and structural suggestions. As such, some of the principles of health education material[101] were ignored– for example, the amount of white borders showing - but guidelines regarding font size and readability scores were followed.



Figure 3.3 Snapshot of PDF file, Photo sheet page 1

Some common elements and headings were held across the different months, so that the mothers could see how certain postures and activities were being upgraded on a monthly basis to provide a more appropriate challenge to their infant's development.

For example, short periods of time spent on the baby's stomach after nappy changes were carried across progressive pages, with suggestions of how to support and entertain the infant in these positions as their tolerance increased. Then at five months a progression was made to have the stomach time on the floor rather than the change mat/compactum for safety reasons. This is indicated in the photographic 'story' that is being created.

Another common thread is the use of similar headings for each upgraded activity. Likewise, arrows are used in a consistent manner, to indicate facilitatory points of control and handling techniques or cautionary notes.

In total, ten photo-sheets were created, with two pages each for:

- two to three months (Appendix B 1 & 2),
- three to four months (Appendix C 1 & 2),
- four to five months (Appendix D 1 & 2),
- five to six months (Appendix E 1 & 2) and
- over six months (Appendix F 1 & 2).

The final sheet was created to be a maintenance programme in case there was a delay in reassessment of the intervention group infants, for logistical or circumstantial reasons.

The photo-sheets were divided into age bands in order to provide structure and a starting point for the nurses, however, they could

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also be used flexibly and if an infant was not managing an activity at their age level, the previous photo-sheet could provide reference and grading.

3.3.2 *Pilot study 3: Final Content Validation*

To validate the content and acceptability of the photo-sheets, they were forwarded to one physiotherapist and one occupational therapist who had assisted in the previous stages of validation of the programme.

Comments regarding the applicability of the pictures, ease of understanding and therapeutic factors, such as correctness and safety were invited. Suggestions were then incorporated into the photo sheet design, with the main changes relating to specific handling points.

These two therapists continued through the process of making the photo-sheets, providing critique of the photographs and layout as it pertained to text and labels of facilitation points for the parents. Several interviews, with each therapist, were held through the process of making the photo-sheets to ensure the faithfulness of the photo sheets to the original programme. This continued and intensive interaction ensured content validation was an ongoing process until the photo-sheets were finalised.

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Figure 3.4 Initial facilitated sitting



Figure 3.5 Corrected facilitated sitting

As an example of the process these photographs are provided. The therapists felt that the early photographs, (Figure 3.4) might have been misinterpreted to suggest that the upper arm of the baby is facilitated by pulling it because of the position of the mother's hand, and so it was suggested that that photograph be retaken with more overt guidance of the trunk, as it is in Figure 3.5

Since arrows were used to show the mothers where to place their hands to facilitate movement, these could be moved, at the

prompting of the expert therapists, to be more specific or helpful. Other changes addressed terminology of the instructions to reduce the amount of text on the sheets, but to maximize the message conveyed. Some changes to activity structuring occurred on a few of the latter pages and photographs were retaken with a different infant in order to ensure that the infant in the photograph was still appropriate age. This served as a sifting process too, as one activity in particular (a play position with the mother lying on her side on the floor and the infant using her body for support in upright kneeling) looked awkward, no matter how many pictures were taken, and it was therefore excluded. (Figure 3.6)



Figure 3.6 Rejected Position

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Part B: Research Methodology

This section describes the study design, the study population, as well as describing how the sample was selected and how data was collected. The methods used for data organisation and processing are also clarified.

3.4 Study design

The design of the study involved a quasi-experimental comparison between groups of infants that were treated using the IPCP and those who were not. It involved 13 Well Baby practices at which babies who slept supine were recruited into either a usual care or intervention group. The IPCP was then given to the intervention group to address the time in the prone position.

The study was a quantitative comparison and can be considered quasi-experimental because the individuals enrolled could not be randomly assigned,[45] but had to be assigned by cluster. Thus Well Baby clinics chosen for this study were assigned to either an intervention group or a usual care group. Seven clinics participated in the intervention group, while six served as a usual care comparison. Practices were randomly assigned as either intervention or usual care, and cluster samples of mother/infant dyads were drawn from their client base.

The aforementioned approach results in a less rigorous investigation, as extraneous factors, such as the personality traits or teaching skills of the nurses, could impact on each group. However, cluster sampling was the most practical means available to prevent contamination of the sample due to mothers comparing what they had been taught at a clinic.

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The research required at this stage of programme development was a small, exploratory trial (Phase II)[77] which would provide a controlled investigation of the efficacy of the intervention.

There is a single categorical independent variable being tested, namely the developmental programme (IPCP), embedded into the ADL of parents.

The study design was also a blinded study, as the researcher was not aware of which group the infants belonged to either at baseline or at follow-up assessments. Blinding was maintained through the use of codes until after the data was analysed. Codes were assigned to infants by a research assistant.

3.4.1 *Study Setting: Well Baby Clinics*

Nursing sisters at Well Baby Clinics were a natural source of information regarding stimulation and infant development. From the time of birth they saw the parents on a regular basis until the infant was a year old. During these routine visits they gave vaccinations, weigh the infants and provide advice regarding feeding and nutrition. They were a normal conduit for information that is pertinent to development and stimulation. As such, mothers perceive the information as being reliable.[111]

Conversely, the referral of a young, normally developing infant to a therapist may seem alarming to a mother. It was for this reason that the Well Baby clinics were chosen for the study setting.

3.5 Study Population and Sample Selection

The study was conducted using a sample from a population of parent/infant dyads involving typically developing, healthy infants, who were placed in a supine position to sleep and were between 8 and 28 weeks old.

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Nurses were recruited to assist with the identification of suitable, normal, supine sleeping infants whose parents would be recruited to take part in the study and also the dissemination of the IPCP in the case of the intervention group.

3.5.1 *Selection of nurses at Well Baby Clinics*

Convenience sampling was used whereby maternity wards in private clinics in the northern suburbs of Johannesburg were contacted and asked to whom they referred mothers to following discharge from the unit. All the clinics provided the names of nurses to whom they routinely referred the mothers, or the name of the paediatricians who had nurses at their offices.

Initial contact was made with all referrals, at which time the aim of the research project was explained. Follow-up appointments were made with the nurses to further explain the research and to determine whether they would be prepared to participate. On occasion the nurses knew of others who they felt may be prepared to participate and contact was made with them too, thus using snowball sampling.

Private Well baby clinics were adjudged to have a higher consistency of return visits, than clinics held in pharmacies or municipal facilities, as nurses operating their own practices are more likely to try to establish a relationship with their clients. This relationship building is a positive factor in trying to reduce attrition of the sample.[112]

Furthermore, in limiting the practices used to those who charge for their services, the likelihood of the several inter-related influences that poverty has on motor development is reduced.[48, 55, 113] Municipal and government hospitals in South Africa serve a wide variety of socio-economic groups, which introduces a wide range of complicating factors. The assumption was also made that mothers

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who were prepared to pay for a service have a certain degree of health literacy, and were persuaded that the service and advice was valuable.[100]

The following formed the basis for the inclusion or exclusion of nurses from the Well Baby clinics:

3.5.1.1 Inclusion criteria:

- Nursing sisters who saw infants for their postnatal vaccines and weight follow ups were included.
- Nursing sisters who agreed to participate.

3.5.1.2 Exclusion criteria:

- Nursing sisters who were not providing advice to mothers based on the principles of the "Back to Sleep" campaign.
- Nursing sisters who were not prepared to be trained in the postural control programme.
- Nursing sisters who were not potentially able to fit teaching of the programme into an appointment (that is, if their appointments were routinely very short).

Four of the nurses at the 15 Well Baby clinics that were contacted, declined to participate. Two others agreed initially to an appointment, but then could not commit to a time and so contact was lost. In the end the nursing sisters at 10 clinics agreed to participate and signed a consent form (Appendix G).

During the weeks of parent enrolment it became apparent that the nurses were finding it difficult to secure the mothers' participation. It appeared that the mothers were reluctant to commit to the programme for a long time period. A further three practices were therefore approached and agreed to become involved.

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3.5.2 *Selection of Mother-infant Dyads*

It was intended that each practice would ask all the mothers of eight week old infants whether they would be prepared to participate in the project, until such a time as five mothers and their babies had been enrolled per clinic. This would have resulted in a sample size of 50 mother/infant dyads (25 usual care, 25 intervention). This is the statistically determined sample size required to detect a difference between the groups, working at a 90% power and a 0.005 level of significance when testing on the Peabody Developmental Motor Scales – 2nd Edition (PDMS-2).

Consent forms for the study were signed by the mothers and left with the nurses (Appendix H and I). In order to improve the rigor of the study nurses asked all mothers, presenting at their practices for their first vaccinations, to participate. They did not purposefully select candidates who appeared more co-operative or sympathetic to the subject matter.

The following inclusion and exclusion criteria were used, in order to select mothers from the appropriate population:

3.5.2.1 Inclusion criteria:

- Mother/infant dyads of healthy, 8 week old infants who slept in supine or in side-lying position 90% of the time,
- Mother/infant dyads who were willing to participate in the study
- Mother/infant dyads where the infants were considered to be typically developing if the attending parent reported that this was the paediatrician's finding at the infant's 6 week appointment.

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3.5.2.2 Exclusion criteria:

Infants were excluded from the study if

- The infant was born before 37 weeks gestational age,
- The infant had had any reported illnesses or prolonged hospital stay that may have resulted in developmental delays or neurological insult,
- The infant had any orthopaedic, muscular, neurological, genetic or metabolic conditions that may have affected motor development,
- The infant was placed prone to sleep or if the sleep position inconsistently included a combination of prone and supine sleep positions,
- The mothers were unable to complete the diary and questionnaire for language reasons,
- The mothers intended to attend a mother/infant stimulation group which addressed motor development during the duration of the research.

3.6 Ethics

Ethical clearance was granted by the Committee for Research on Human Subjects, University of the Witwatersrand, Ethical Clearance certificate number M070831 (Appendix J).

The parents were assured of the following when they were initially approached:

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- Participation was completely voluntary and they could withdraw at any time.
- The services from the clinic would not be changed or negatively affected for those parents who chose not to participate.
- The contact details and names that were needed, in order to facilitate the assessments, would be held by the researcher only.
- The list that linked names and research codes would be held by the research assistant only. This was the only list that linked the infant with the raw data.
- In the event that any of the infants was significantly developmentally delayed, feedback would be given to the parents and recommendations regarding follow-up would be made.
- Also, participants who requested feedback, would be given the results of the assessment.

The information sheet provided for nurses and their informed consent is provided as Appendix G.

The information sheets for the mothers and their informed consent appear as Appendix H and Appendix I.

The Biographical Questionnaire completed by all parents is included in Appendix K.

3.7 Research Procedure

3.7.1 *Randomisation of clinics*

Clinics that were enrolled in the study were randomly assigned to the usual care or intervention groups by means of a randomization

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table.[44] Since 10 clinics/nursing sisters agreed to participate initially, five practices were randomly assigned to the intervention group cluster and five to the usual care group cluster. When three additional practices were recruited, two were randomly assigned to the intervention group cluster and one to the usual care group cluster. Although a total of 13 clinics were involved, functionally, there were only six control practices and five intervention practices as two of the nurses failed to enrol any mothers at their clinics.

As a result, all the mother/infant dyads at a given practice were in the same group creating a cluster sample of infants. This was done in order to prevent cross contamination between mothers at the same practice and to reduce the possibility of the sisters at the clinics accidentally providing the incorrect intervention to parents in different groups.

3.7.2 *Training of nurses*

Nursing sisters from the Well Baby clinics assigned to the intervention group were trained in the IPCP in order to teach the intervention. It was initially planned to train all of the nurses at one training session so that the information that everyone received was the same. However this proved impossible to arrange because of conflicting schedules and availability of the nurses outside of their normal working hours. As a result the nurses were individually trained by the researcher, at times that were suitable to their working hours. The disadvantage of this situation is that the information taught would be similar, but not identical.

The nurses were given a training guide (Appendix L) which was broken into an instruction sheet for each month of the programme with a summary of the milestones for each month. The guide contained the activities or postures, examples of when these could be used, key points of facilitation to ensure the correct movement and

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ideas to up- or down-grade the activity in case the infant was already coping easily with it or was not yet ready for the task in any given month.

The nurses were also taught basic principles for the programme as a whole, to convey the message to the mothers that they should have fun with their infants and watch their infants' reactions to the tasks rather than be dogmatic about the inclusion of all positions and fixated on milestone achievement.

The nurses had access to the researcher by telephone and regular contact and were free to ask questions regarding the programme throughout the duration of the research.

3.8 Outcome Measures

3.8.1 *Screening Questionnaire*

A screening questionnaire, developed by the researcher, was used to determine whether the infants were appropriate for the study. (Appendix K)

The screening questionnaire looked at the gestational age at birth, birth weight, length and Apgar scores, where the baby was born and any signs of difficulty at birth (prolonged foetal distress, birth apnoea, 'blue baby', need for oxygen, floppiness, stiffness, need for incubation etc.). The mothers were asked if they attended, or were intending to attend a mother/baby stimulation group.

The questions regarding the birth history were included to determine whether the baby suited the inclusion criteria for the study. Infants who were ill at birth, premature or who were born by emergency caesarean (suggesting foetal distress or a risk for birth hypoxia) would be excluded.

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The questionnaire was also designed to draw out information regarding how the baby was positioned to sleep, who first told the mother how to position the baby for sleep and who the primary caregivers were.

The questionnaire was piloted using a group of 5 mothers, not participating in the study, attending a Mothers and Babies group. Adjustments to the questionnaire were made based on any ambiguity that they reported, or if the question elicited information from the mothers that was not anticipated or relevant.

3.8.2 *Baby's Day Diary©*

The use of diaries to research baby development has a long history[91] and allows parents to tell the narrative of their infant's activities reliably. It is preferable over retrospective memory of the day or events.[16]

The Baby's Day Diary©[114-116] was used with permission of Dr R Barr (Appendix M). The diary makes use of 'time rulers' in 5 minute intervals, which are shaded according to a key chart, depending on the infant's behaviour during that time. Arrows recorded above the ruler allow the person completing the diary to indicate the position in which the baby went to sleep. The diary has been created in order to provide parents with an easy means of recording the activities of their infants as they happen, or soon thereafter.

The diary was shown as a reliable means of recording infant crying in research,[114] using parental records via the diary and external recordings using audiotapes. The results showed a high correlation between what the parents recorded and what could be objectively measured on tape. The authors noted that the diary is limited when parents are not well motivated and is best used when the parents record events on a regular basis throughout the time period. The

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diary has since been used to measure other infant behaviours such as crying related to carrying and crying related to feeding and infant position.[16]

The Baby's Day Diary© was adapted to meet the objectives of this study (Appendix N and O, each day 1 out of 3 days). Barr's research assistant changed the coding, from a key chart relevant to infant crying to the pertinent information regarding infant position. A separate diary was created for the usual care and intervention groups, as the instructions for the intervention group also included a request to mark off activity participation.

The Baby's Day Diary©, as it is designed for this study, therefore elicits information regarding the infant's behaviour and the infant's position over a 24 hour period. It records information as to whether the baby was asleep, awake or feeding (with a code if parent could not remember) and when awake, whether the baby was held or carried, sitting with support, sitting without support, lying on their back/side or lying on their front. Information was also obtained regarding the position in which the infant went to sleep in by the use of an arrow above the ruler. The parents in the intervention group were also asked to place an 'X' above the ruler each time they incorporated an activity or posture that was on the photo-sheet.

All parents were taught how to use the diary by the researcher at the time of the baseline assessment. There is a standardised format for this training and an instruction sheet that is provided by the original author (Appendix P).

3.8.3 *Peabody Developmental Motor Scales – 2nd Edition (PDMS-2)*

The PDMS-2 is a standardised assessment tool which provides normative data for developmental categories. It is a widely used, therapist driven, assessment tool which assesses gross and fine

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motor development in infants from birth to 7 years of age. The PDMS-2 comprises 3 subscales, yielding age standardised normative quotients for Gross Motor Quotient (GMQ), Fine Motor Quotient (FMQ) and a Total Motor Quotient (TMQ). It can be used to determine which fine and gross motor skills a child has mastered, and which are immature for their age.[109, 117] The items on the test have a three point scoring system, resulting in a score of 0, 1 or 2 depending on a description of the quality of the movement, as defined by the authors, in the testing booklet. The test procedure creates a basal and ceiling effect which gives the total score. This raw score is then converted to a standard score using age stratified, normative tables. The standard score is recorded on a Profile/Summary sheet. Quotient scores are created for GMQ and FMQ using the sum of the raw scores related either to a gross or a fine motor skill. The TMQ is the sum of all the raw scores, converted to a quotient by means of a table (Table B1 of the manual.[109])

The assessment is rated highly for reliability and validity and is widely used to assess infants for developmental delay,[16, 118] because it allows for a qualitative evaluation of emerging skills rather than a 'yes/no' checklist of skill competence. Inter-rater reliability (r = 0.96 for the overall test) and test-retest reliability (r = 0.89 for the overall test) are high.[119] Content validity is assured with an internal consistency α = 0.97.[109, 119] The test can be used as a measure of change over time in a pre- and post-intervention evaluation.[119]

3.9 Method of Data Collection

3.9.1 *Sample selection and Screening questionnaire data*

Nursing sisters approached all mothers of eight week old infants who attended their clinic for vaccination and weighing. An information sheet and consent form with biographical screening questionnaire

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was given to each mother to inform them about the study and to explain the process (Appendix H and I).

The mothers read the information sheet while they were waiting for their appointment, and those who agreed to participate, were asked to complete the consent form and biographical questionnaire at that time and to leave them with the nursing sister (Appendix K).

Biographical questionnaires and consent forms were collected from the Well-baby clinics, by the researcher, in sealed envelopes, so that the names of the parents would not be directly associated with the clinic from which they were gathered. These were collated and checked by a research assistant to ensure that they met the requirements for the study. Mother's names and contact details were placed on a single list in no particular order. Appointments, to complete the baseline assessment, were made as soon as the researcher was given the names of the mothers. The researcher was therefore blinded as to which group the parents came from and mothers were asked not to reveal which clinic referred them for the study.

3.9.2 *Assessment of infants*

At the time of the baseline assessment, infants were assessed with the PDMS-2. Raw scores were recorded at the time of the assessment, then converted to standard scores and plotted on a Summary/Profile form. Some of the assessments were done as a home visit and some were scheduled to take place at the therapy rooms of the researcher, depending on the preference of the mother. The assessment requires a table and minimal floor space to complete. A consistent set of toys (rattles, cloth, ball, soft toy, pull toy and paper) were used with the infants, but if the child was not responding to these, their own toys were also employed to elicit the responses

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required by the PDMS-2. The infants were assessed as soon after being recruited into the study as possible.

At the appointment for the baseline assessment, all parents were taught how to complete the diary pages by the researcher, using the standardised format supplied by Barr (Appendix P). As there was a difference between the diary pages for the two groups, the first set of diary pages to be given to the parents by the researcher, was contained in sealed envelopes, prepared by the research assistant, so that blinding was ensured for the researcher. Subsequent pages were left with the nursing sisters and the parents received a new set with each monthly visit. For those parents enrolled in the intervention group, this coincided with the teaching of the new activities and the receipt of the monthly photo sheets.

All diary pages were collected by the researcher for logistical purposes, after having them placed in sealed, unmarked brown envelopes by the nursing sisters. A collection run of all the clinics was done on a single day, on a monthly basis, so that no one clinic would stand out (as it might if collection was individual). The envelopes were returned to the research assistant who replaced the name of the baby with a code so that diary pages could be analysed without affecting the blinding of the researcher.

Reassessments were scheduled to take place at 28 weeks. Developmental data after this time would have been affected by infant choice, as infants begin to make their own choices, regarding sleeping position, between five and six months.[61]

All the infants were reassessed using the PDMS-2 and the follow-up scores were plotted on the Summary/Profile Form. Appointments were made by the researcher as soon after the infants were 28 weeks as possible. In the case of some of the babies, recruited late in the enrolment process, the reassessment fell over Christmas and so

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appointments were made as early in January as possible. These infants were scored for an older age on the PDMS-2.

3.10 Data processing methods and Data analysis

3.10.1 *Organisation of Data*

Data from the biographical questionnaire, PDMS-2 Examiners Record Booklet and Profile/Summary Form and Baby's Day Diary® were coded into numerical values using several Excel spread sheets.

These were organised as:

- Demographic information: age, gestational age, weight and length, position in the family and number of siblings of each individual infant, and were arranged by group (intervention or usual care)
- Raw scores for the baseline assessment and follow-up assessment were recorded and arranged by group.
- Quotients (FMQ, GMQ, TMQ) for both assessments were generated by calculating the sum of the scores and converting to a quotient. These were also arranged by group.
- Diary data, listed by individual, with a sum of the minutes in each category per day of the set. For the sets of 3 days, an average time was calculated to allow for variations in daily occurrences and non-typical days. Thereafter, a summary page was created that clustered Diary sets together by age and group (i.e. diary set 1 for the usual care group versus Diary set 1 for the intervention group)

Diary data was then converted to averages of each set and represented as comparative graphs. The diary set with no comparative data was represented as a pie chart.

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3.10.2 *Statistical Methods*

Descriptive statistics were used to describe, summarise and organise the results obtained from the assessments.

The raw scores and quotients were used to generate means, ranges and standard deviations for the various variables using an Excel spread sheet. This data was used in further analysis.

Groups were compared at baseline using Student's two-sample t-test to assess randomization and these results were also confirmed using Wilcoxon's rank-sum test because of the small sample sizes. The change from baseline to follow-up was also assessed between groups using Student's two-sample t-test, however, an analysis of covariance (ANCOVA) with baseline value as covariate was also done. Furthermore, in a rather exploratory way, within group change was assessed with Student's paired t-test. Testing was done at the 0.05 level of significance.

Statistical analysis was conducted from the means using the "Strata" computer programme.

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