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On behalf of the PROFEG-group

Routine Iron Prophylaxis during Pregnancy

Effects on Maternal and Child Health in Maputo City
and the urban part of Maputo Province Mozambique
(PROFEG)

Report of the pilot study
August 2007



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Layout: Christine Strid

ISBN 978-951-33-2086-7 (soft cover)

ISSN 1795-6897 (soft cover)

ISBN 978-951-33-2087-4 (PDF)

ISSN 1795-8202 (PDF)

STAKES, Helsinki 2008

Valopaino Oy

Helsinki 2008

Abstract

Saara Parkkali, Fátima Abacassamo, Graça Salomé, Orvalho Augusto, Minna Nikula, PROFEG-group. Routine Iron Prophylaxis during Pregnancy. Effects on Maternal and Child Health in Maputo City and the urban part of Maputo Province Mozambique (PROFEG). Report of the pilot study, August 2007. STAKES, Discussion Papers 1/2008. pp. 28, price 10 €. Helsinki 2008 ISBN 978-951-33-2086-7

Background

This report gives the basic results of the pilot study from a trial “Routine Iron Prophylaxis during Pregnancy – Effects on Maternal and Child Health in Maputo, Mozambique”. The objective of the trial is to compare two iron administration policies during pregnancy in regard to health and program feasibility, routine iron prophylaxis vs. screening of anaemia and therapy with iron in areas with endemic malaria and high prevalence of HIV infection. The influence of iron prophylaxis on pregnancy outcomes in developing countries remains unclear.

Subjects and Methods

The study is a pragmatic, non-blind randomised controlled trial. Women are randomised individually into two different study groups, routine and screening & therapy. The pilot study was carried out between November 2006 and April 2007 in Maputo city in the health centre of 1o de Maio, with the objective to test the study procedures and the data collection process. Total of 781 women were recruited on their first antenatal visit and by April 2007, 134 women were followed up until delivery. Women were randomised into the study groups, recruited, and data collected by trained study nurses. Women in the routine group received iron prophylaxis as usual in antenatal care and the therapy group received iron therapy, if the haemoglobin measurement was below 9g/dl.

Results

We collected the data of the women on recruitment, on subsequent visits and after delivery. The average number of women recruited per week was 43 women. The foremost areas of residence of the women were Maxaquene (53%) and Polana Canhico (39%). The mean age of the participants was 24 years. Anaemia prevalence (Hb < 9g/dl) in the therapy group was 36%. The deliveries (n = 134) occurred in the health centre of 1o de Maio and in Mavalane hospital, deliveries in the central hospital were not traced in the pilot.

The setting up of the pilot study was time consuming and administrative issues and authorisations took longer than expected. Several practical obstacles had to be solved. The main procedures were not modified, but data collection forms were modified slightly.

Keywords: maternity care, prenatal care, randomised controlled trial, iron prophylaxis, Mozambique

Table of contents

Abstract

1	INTRODUCTION.....	7
2	RESEARCH SETTING	8
	2.1 Study area and population	8
	2.2 Antenatal care and work practices	9
	2.3 Within the laboratory of the health centre.....	10
3	PILOT STUDY	11
	3.1 Objectives.....	11
	3.2 Study design	11
	3.3 Randomization and recruitment	11
	3.4 Data collection	13
	3.5 Administration of iron and folic acid.....	13
	3.6 Haemoglobin measurement.....	13
	3.7 Follow up visits	14
	3.8 Delivery	14
4	RESULTS.....	15
	4.1 Flow of women in the antenatal system in Health Centre 1° de Maio	15
	4.2 Recruitment by April 2007	16
	4.3 Compliance to group allocation	17
	4.4 Profile of the study participants.....	17
	4.5 Haemoglobin measurements with HemoCue.....	21
	4.6 HIV Infections	22
	4.7 Deliveries.....	23
5	PRACTICAL EXPERIENCES.....	26
	5.1 Constraints during the preparatory phase	26
	5.2 Constraints during the pilot implementation phase	26
	5.3 Strengths.....	27
	References.....	27

1 INTRODUCTION

This report gives the basic results of the pilot study of Routine Iron Prophylaxis During Pregnancy – Effects on Maternal and Child Health in Maputo City and urban part of Maputo Province in Mozambique. The pilot was carried out between November 2006 and April 2007 in the *1º de Maio* health centre in Maputo city. This is the first report of the Routine Iron Prophylaxis research project. This report describes the working phases from preparation of the protocol until the end of recruitment of the pilot study, and describes some results.

The research is situated within the context of a collaborative triangle between researchers from the Community Health Department of Eduardo Mondlane University Medical Faculty, the Mozambican Ministry of Health and STAKES (National Research and Development Centre for Welfare and Health) in Finland. The research is financed by the Academy of Finland, grant number 210 631, health research unit.

The project consists of three interlinked phases, the preparatory phase, pilot study and the trial as such. The research project started in April 2005 with the preparatory phase: identifying Mozambican partners to work in collaboration with STAKES, writing the research protocol and the approval of the protocol. In the second phase, the pilot study was carried out, which tested the data collection process and the procedures described in the study protocol. The third phase, trial proper, is currently ongoing and is not covered here.

The overall goal of the study is to compare two policies in iron administration during pregnancy with respect to health outcomes and program feasibility, routine iron prophylaxis vs. screening & therapy with iron, in an area with endemic malaria and high prevalence of HIV infection.

2 RESEARCH SETTING

2.1 Study area and population

The pilot study was carried out in the *1º de Maio* health centre. This health facility, located in Maputo city, it provides primary health care to 59 281 people as part of the network of national public health sector. The centre is part of the Mavalane cactment area that covers a population of 494 011 (2003–2004) and consists of 7 health posts, 7 health centres and the General Hospital of Mavalane (reference Hospital) [1]. The Health centre lays 4 Km from the reference hospital. Women can attend antenatal services and deliver at the maternity ward of the health centre. Antenatal care is open for daily consultations during weekdays and the maternity ward is open for 24 hours every day. The Map shown in Figure 1 depicts the area of Mavalane.

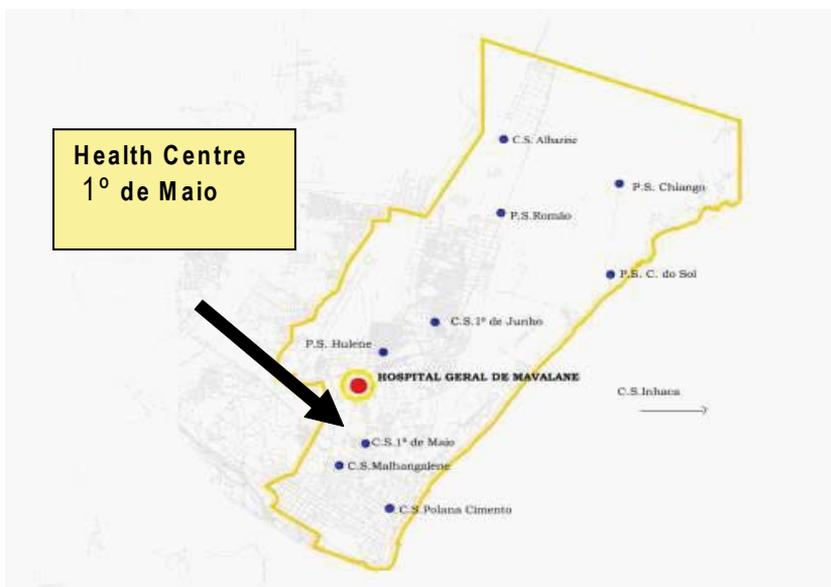


FIGURE 1. Map of Mavalane area. The black arrow shows the 1º de Maio Health Centre

Health posts do not have facilities for women to deliver and they do not provide antenatal care. From antenatal care, women who are found to have more complicated situations are usually referred from 1º de Maio to Mavalane Hospital. In its turn, Mavalane Hospital can also refer to the Maputo Central Hospital (national reference and university hospital) (Figure 2). Both Mavalane and Maputo Central Hospital (HCM) perform caesarean sections.

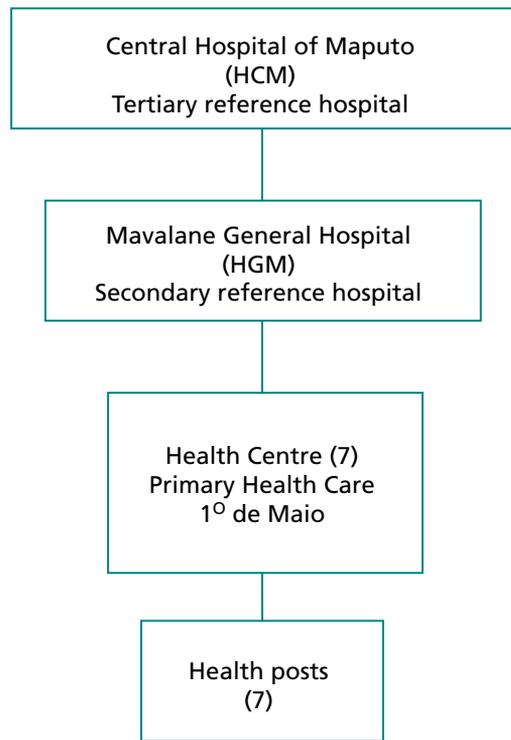


FIGURE 2. 1° de Maio Health Centre and the flow of patients as part of national network

2.2 Antenatal care and work practices

Antenatal consultations and assistance during delivery in 1° de Maio is carried out by mother and child health (MCH) nurses. Antenatal consultations in Mozambique are recommended from the third month of pregnancy onwards. Pregnancy is calculated from last menstrual period (LMP) - when it is known, with the help of an obstetric calendar. When women do not know their LMP, gestation length is calculated by measuring uterine height and by palpation. Antenatal visits are recommended at intervals of one month and a woman is considered assisted in the antenatal program if she completes 5 antenatal visits. [2, 4]

Women who come for their first consultation with pregnancy of less than three months are not seen and are asked to return only after the pregnancy becomes visible. It is not a routine to perform pregnancy tests in the antenatal care. If there are problems with the pregnancy prior to 3 months of gestation and the woman wants to enrol in antenatal care she is referred to the reference Hospital for an ultrasound to verify the pregnancy and possible problems.

All women usually arrive at the health centre at the same time, as early as 6–7 am and the antenatal consultations are usually finished by 13 pm. Women first receive collective health education from the routine MCH nurse. The collective health education consists of HIV information (including counselling), information about the importance of vaccination coverage with anti-tetanus vaccine during pregnancy and diet advice. After receiving health education women coming for their first visit are attended by an MCH nurse, the antenatal consultation. The antenatal form is filled out and an HIV test is done (voluntary testing). After the individual consultation women go for tetanus vaccination. Three doses of tetanus vaccine are recommended, the first by the fifth month of pregnancy, the second by the seventh month and the third after

delivery. After the individual consultation and vaccination, women go to the laboratory for blood tests (syphilis, haemoglobin and blood group is determined).

On subsequent visits, women are often seen by a different MCH nurse.

HIV counselling and testing in antenatal care was earlier done by separate nurses but during the pilot study this changed. The MCH nurse counsels and does HIV testing in the antenatal consultation. The general trend in Mozambique for HIV care is to integrate it into the routine health care system to avoid parallel care for HIV positive mothers.

2.3 Within the laboratory of the health centre

Haemoglobin is routinely requested only during the first antenatal visit. In circumstances when women present clinical signs of severe anaemia, detected during a subsequent antenatal consultation, she is asked to go for another haemoglobin test in the laboratory. Haemoglobin is measured at the health centre by a colour comparison method, *Lovibond*[®]. The *Lovibond* is based on the visual comparison of the colour that results when an accurate measurement of blood is added to a diluting fluid. The colour of the test solution is visually compared with a colour disc that matches the diluted haemoglobin fluid. The intensity of colour in the test solution corresponds to a specific haemoglobin level.

3 PILOT STUDY

3.1 Objectives

The objective of the pilot study was to test the data collection process and the data collection forms. The recruitment for the pilot study was carried out between November 2006 and April 2007 within antenatal care in the 1º de Maio Health Centre. A total of 781 women were recruited and 134 women were followed up until delivery.

3.2 Study design

The study used an experimental design, a pragmatic randomised controlled trial. Women were randomised individually and the group allocation was non blind.

3.3 Randomization and recruitment

The target population of the pilot study were pregnant women attending antenatal care in the 1º de Maio Health Centre. Exclusion criteria were women under the age of 18 years and women that were identified as a high obstetric risk (ARO¹) excluding the criterion of over 35 years.

The primary data collector was a study nurse – an outside nurse employed by the project to exclusively recruit and collect study data. The MCH nurses are the usual nurses working in the health centre and not directly participating in the study. (Figure 3.)

Information about the study was given by a study nurse when the women were gathered in the mornings to receive routine health education by an MCH nurse. After receiving collective information all women on their first consultation were attended first by the MCH nurse and then by the study nurses.

Upon meeting the study nurses the women were assessed for eligibility criteria and asked if they wanted to receive any additional information about the study. Women who were not eligible or did not want to participate were given iron tablets as usual.

Women who accepted to participate were randomized into two groups (1) Routine administration of iron during pregnancy (=routine group) or (2) Screening for anaemia and therapy with iron (= therapy group).

Randomization was done individually by numbered envelopes generated by a computer program; the envelopes contained the study card and informed consent. Before opening the envelope for each woman, her name was written on the envelope. The envelopes were opened in a consecutive order for each woman by study nurses. Informed consent was asked after the envelope was opened.

Women allocated to the routine group had no option to choose to belong to the therapy group. But she could be non compliant with iron prophylaxis, as usual. In the therapy group if the woman did not accept the group allocation she was explained that she could take iron tablets if she wanted. But she was asked whether her data could be collected (i.e. retained in the study). In the analysis these women will be kept in the therapy group, but considered non-compliant. When women did not accept allocation to therapy group the wish to take iron was written on the study card to enable the nurses to see this on subsequent visits and ask the woman again on the next visit if she still wished to continue to take iron. Women in the therapy group, even when

1 ARO is a Portuguese acronym of Alto Risco Obstétrico which means high obstetric risk.

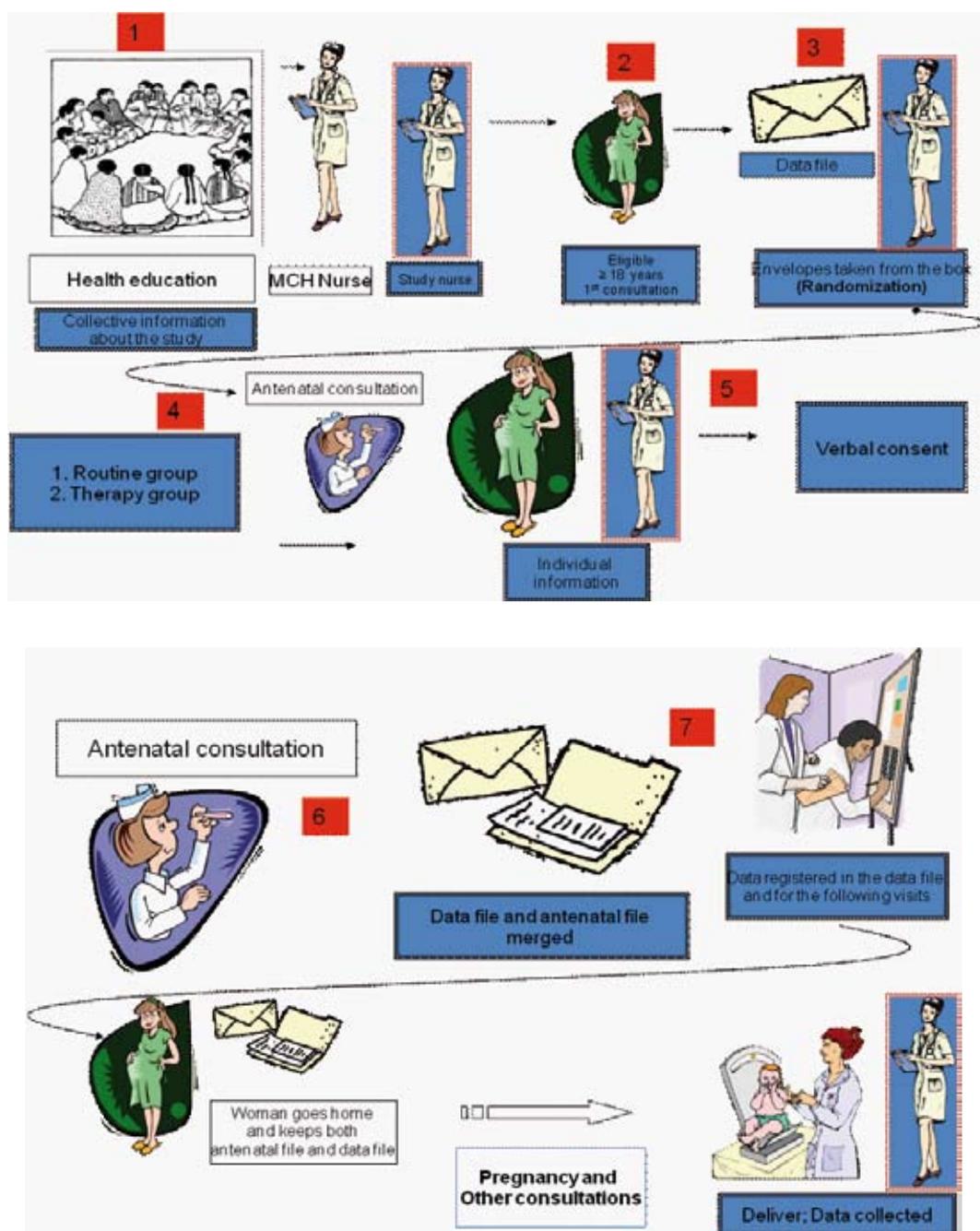


FIGURE 3. How pregnant women become part of the study

refusing group allocation were measured haemoglobin (if they did not deny this), and were given iron therapy for anaemia according to the haemoglobin level.

All women who were recruited signed (or thumb printed) an informed consent form. On recruitment women were given individual information about the study, given a take home leaflet, and the study card was stapled to their antenatal card. A pink study card and information leaflet was used for the therapy group and yellow ones for the routine group.

3.4 Data collection

The data collection forms were elaborated jointly by Mozambican and Finnish researchers. Four different forms were used; 1) First antenatal visit, 2) Subsequent visits, 3) After discharge from the maternity and 4) A form for exclusion from the study.

Data collection was done by study nurses in a parallel system to the routine antenatal care. Women were attended by study nurses after their routine antenatal visit. Most information collected by the study nurses was present in the antenatal forms and copied from there. In addition to copying information from the antenatal form the study nurses asked the women some questions. Routine MCH nurses did not take part in data collection, they were only informing women where they should go and meet the study nurses.

A monitoring form for weekly recruitment was used to monitor the total number of women attending first consultation, number recruited, number of women lost on recruitment, number of refusals and number of non eligible women. The data collected was entered to a database in MySQL server (version 5.0.40) through forms designed in Microsoft Access 2000. For monitoring and analysis purposes the data was imported through ODBC connections to Stata SE 9 and transferred to SPSS through Stat Transfer.

3.5 Administration of iron and folic acid

Iron or folic acid tablets were given to women by the study nurses, also to women who were excluded or declined the study. The study nurses gave the iron or folic acid tablets to all women on their first antenatal visit and on follow up visits only for women who belonged to the study. The tablets were given in a small plastic bag designed for handing out tablets. The combination tablets of iron and folic acid were red in colour and the folic acid tablets were yellow. The amount and type of tablets given was written on the routine antenatal card as well as on the data collection forms by the study nurses.

Women in the routine group received 30 tablets of combination of 65 mg ferrous sulphate + 400ug of folic acid on each antenatal visit with instructions to take one tablet per day. They were advised and encouraged to come back for antenatal follow up and to get another months supply of iron tablets after one month. The routine group did not have their haemoglobin measured by the rapid measure (HemoCue). Women in the routine group were treated as they would be treated normally in antenatal care.

Women in the therapy group received either folic acid or iron according to their haemoglobin levels. They had their Haemoglobin measured on each antenatal visit by a study nurse with a rapid haemoglobin measure (HemoCue Hb 201+). The need for iron therapy was evaluated on each visit. Iron therapy for anaemia was administered if haemoglobin was below 9g/dl with a dose of iron 130mg/day, 60 tablets (supply of one month). If the haemoglobin was \geq 9g/dl women were given folic acid tablets 1mg/day, 30 tablets.

3.6 Haemoglobin measurement

Haemoglobin measurements were done by HemoCue Hb 201+ from the therapy group on each antenatal visit. HemoCue is a quick and simple measure for haemoglobin from capillary, venous or arterial blood by photometry. All haemoglobin measurements were done by study nurses from capillary blood from a sample taken from the finger tip. Haemoglobin level was measured in a total of 617 women (n = 390 therapy group, n = 227 routine group), on the first antenatal visit. Due to a misunderstanding by the study group haemoglobin was measured of some women

belonging to the routine group. Based on these measurements the haemoglobin values were similar in both groups.

3.7 Follow up visits

All women were encouraged to come back for subsequent antenatal visits at intervals of one month. Women belonging to the study were seen first by a routine MCH nurse and then by study nurse. Women not taking part in the study were only seen by routine MCH nurses.

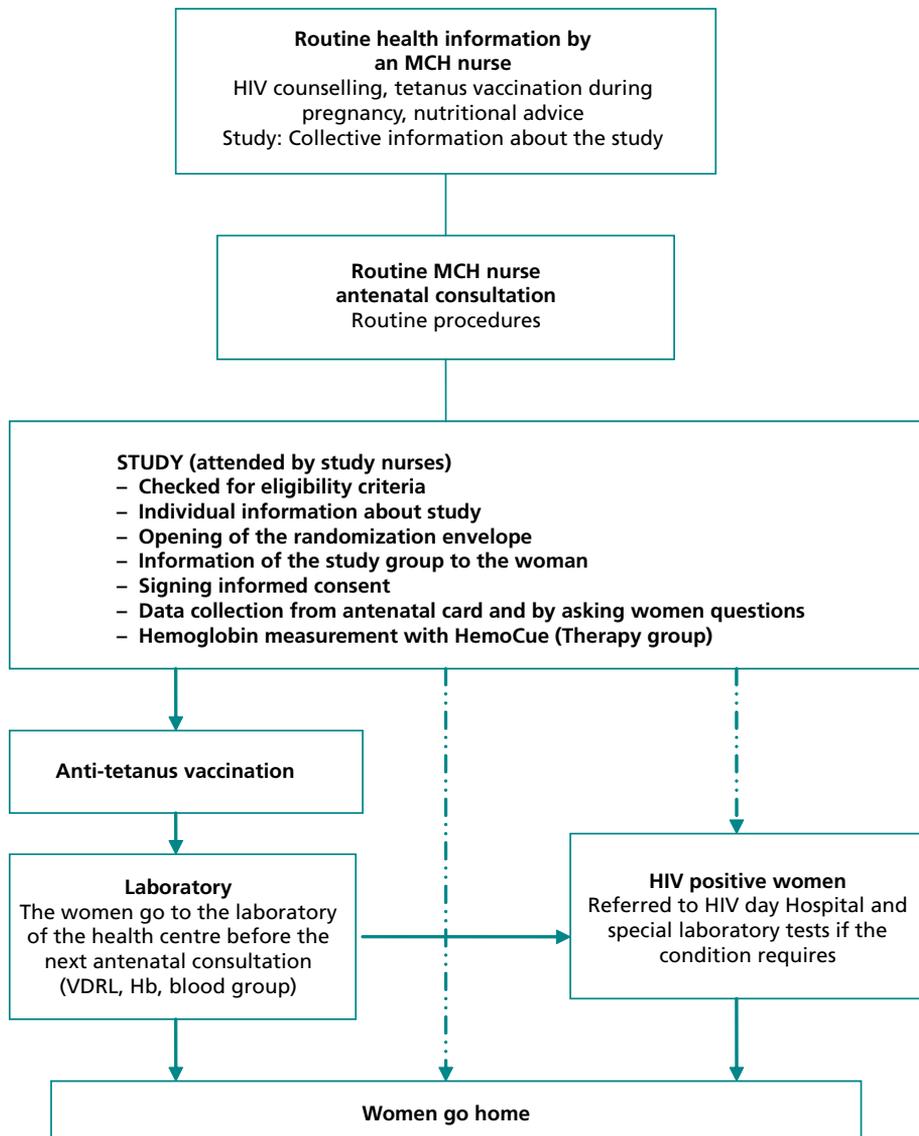
3.8 Delivery

At the time of delivery, routine nurses at the maternity ward of the health centre and of the reference hospital were alerted to identify and collect the visible yellow or pink study cards from the women who came to deliver. The routine nurses separated the study cards and the clinical birth records of women who belonged to the study after the delivery. The study cards and the clinical birth records were stapled together and stored in the maternity ward for later data collection by study nurses or study coordinators. In the health centre's maternity ward, study nurses collected the data, copied information from the clinical birth record to the data collection form. In the reference hospital the study coordinators collected the data from the clinical birth records.

4 RESULTS

4.1 Flow of women in the antenatal system in Health Centre 1° de Maio

Figure 4 demonstrates the flow of women in the antenatal care of the health centre 1° de Maio, the routine practices and the intervention by the study.

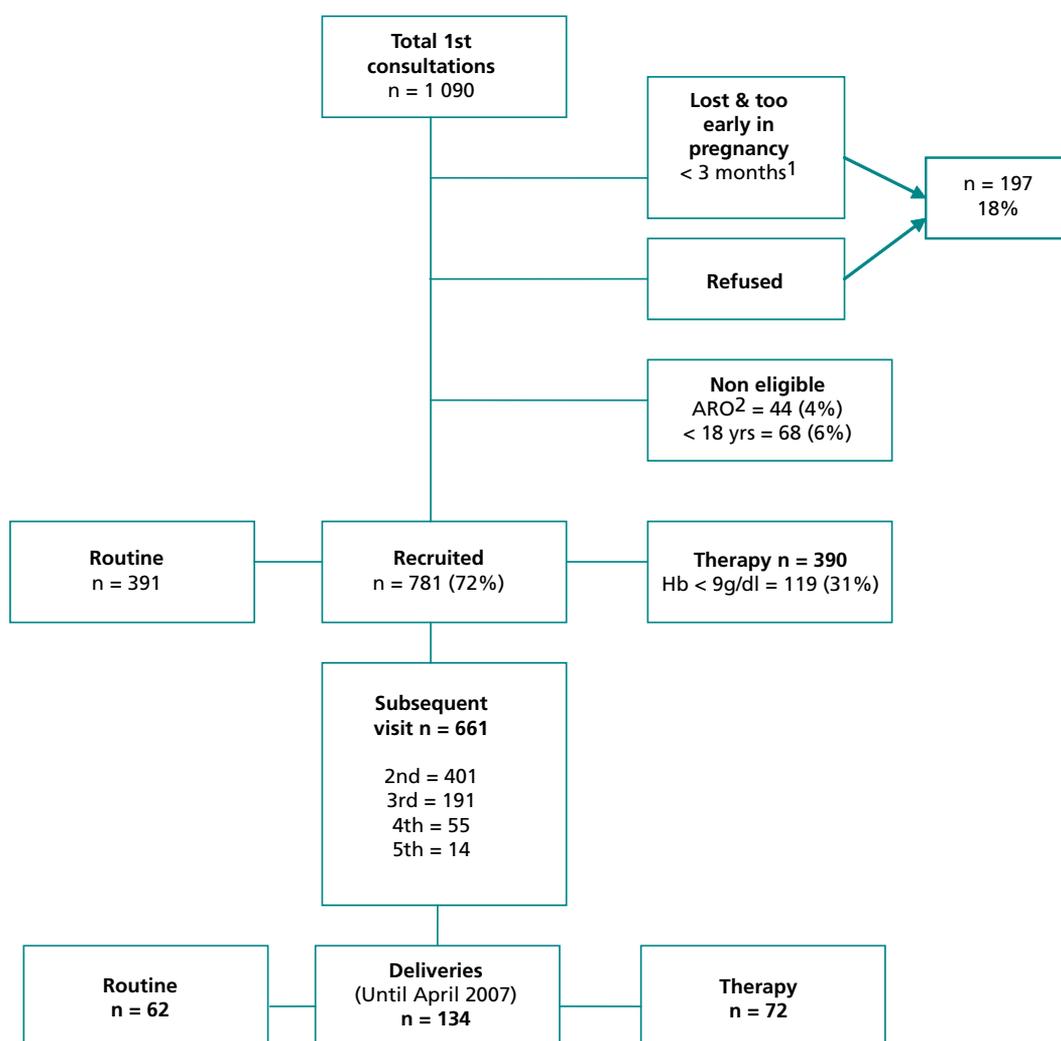


¹ Routine procedures; issuing of antenatal card, identification of high risk pregnancy, obstetric history, requis for laboratory tests (VDRL, haemoglobin and blood group), obstetric examination and clinical data, iron prophylaxis, malaria prophylaxis, intestinal parasite treatment, HIV testing, tetanus vaccination

FIGURE 4. Flow of women in the antenatal care

4.2 Recruitment by April 2007

The numbers recruited in each group are similar. In the therapy group haemoglobin is measured, 36% of the women are anaemic (Hb < 9g/dl). Subsequent visits represent the number of total subsequent visits carried out (second, third, fourth etc). The women that are lost on recruitment is 12%. It is not possible to reliably say how many women did not go and meet the study nurses and how many women had not completed the 3 months of pregnancy to be suitable for antenatal care. Women with less than 3 months pregnancy were sent home by the MCH nurse and were not attended by the study nurse. These women were anyhow counted in the number of total consultations. The difference in number of deliveries in the routine and the therapy group is most probably due to chance (Figure 5).



¹ Lost & too early in pregnancy = Women who did not go to the study nurses, and women that were less than 3 months pregnant (a antenatal card is not “opened” for them) they are counted as women seen by routine nurses but do not go through an actual antenatal consultation.

² ARO = High obstetric risk.

FIGURE 5. Recruitment tree

Reasons for refusal to participate were difficult to obtain, women did not state reasons for refusal but just said they did not want to participate without specifying a reason. There were very few refusals, stated refusals (1%). The numbers of refused and lost are mixed and it is not possible to state accurate numbers for either group, some women did not show up to the study nurses because of misunderstanding or because of refusing to participate.

4.3 Compliance to group allocation

Total of 260 women who had haemoglobin equal to or over 9g/dl, 10 of these wanted to take iron, this means 3.8% belonging to therapy group were non compliant on the first antenatal visit.

There was a peak in numbers of antenatal consultations on the second week of January 2007, and on weeks 10 and 11 of March 2007 (Figure 6).

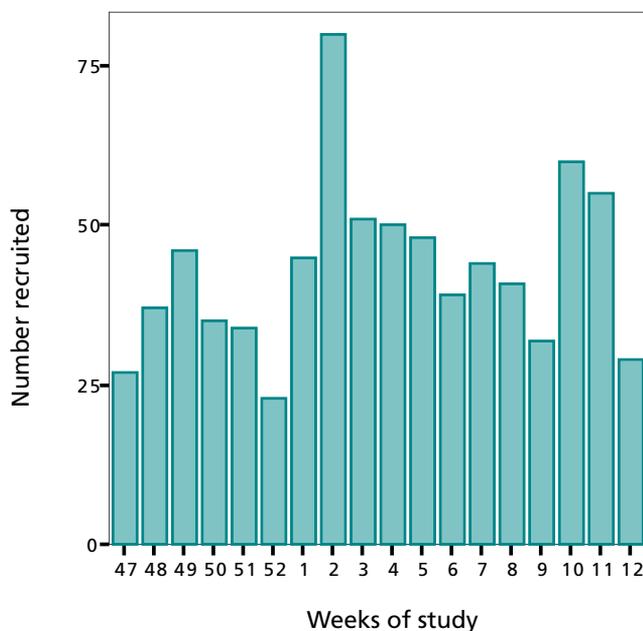


FIGURE 6. Weeks of study and number of women recruited

4.4 Profile of the study participants

Here we present the profile of the study participants and some results. However the number of births is too few to make conclusions or assumptions on the differences and their significance between the two study groups.

The mean age of the participants is 24 years. The age structure is similar in both groups (Table 1).

TABLE 1. Mean age of participants by study group

		Study group		Total
		Routine	Therapy	
Age	Valid N	386	385	771
	Missing N	5	5	10
	Mean	24	25	24
	Std	5,2	5,8	23
	Minimum	18	18	18
	Maximum	40	43	43

Information about the age of the women was collected both by copying the age stated in the antenatal card (the age stated by the woman) and by asking women their date of birth. There was some discrepancy in these ages. We have used the age from the antenatal card. The age distribution can be seen in Figure 7.

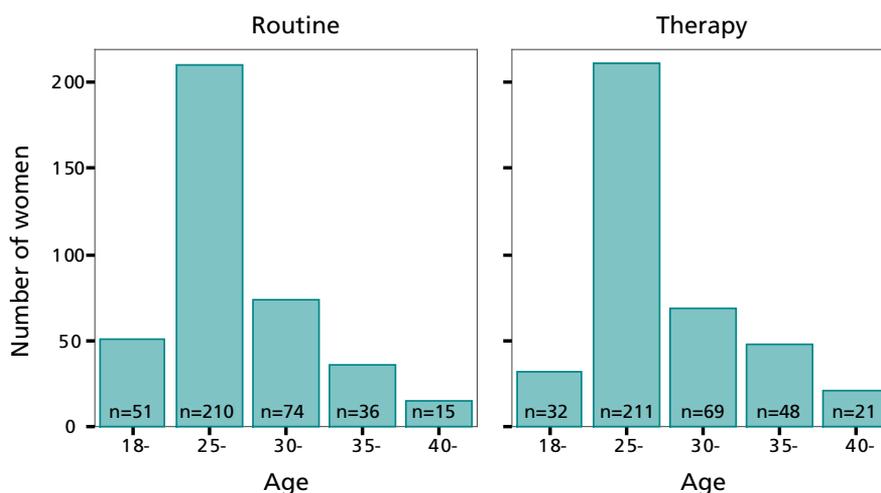


FIGURE 7. Distribution of age by study group

Most women attending the antenatal visits came from neighbourhoods of Maxaquene (53%) and Polana Caniço (39%), the rest (8%) came from various other neighbourhoods around the area. The other neighbourhoods were; Mavalane, Costa do sol, Forças Populares, Malhangalene, Magoanine, Hulene, CMC, Zimpeto, COOP, Mahotas, 25 de Junho, Alto Mae, B. Triunfo, Boane, Chamanculo, Ferroviário, Machava Socimol, Matendene, Patrice Lumumba, these ranged from 0,1% to 1,3% (Figure 8).

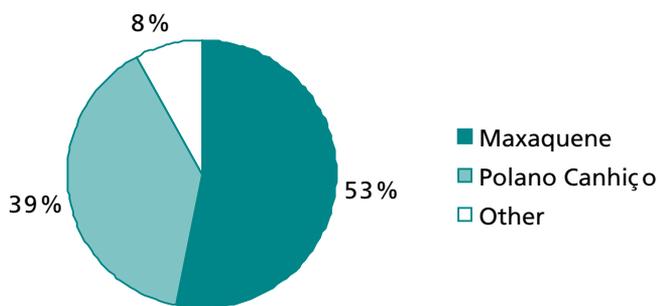


FIGURE 8. Area of residence of women

There were more primigravidae in the routine group 38%, in the therapy group there were 33%. Figure 9 demonstrates the distribution of number of previous deliveries by group.

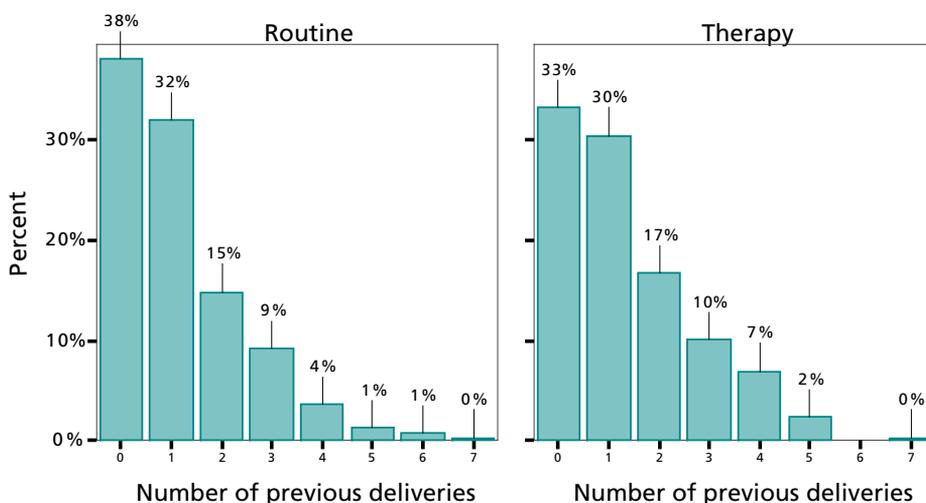


FIGURE 9. Number of previous deliveries by group

The average gestation weeks on the first antenatal visit was 21 weeks. Fifty percent of the women attended their first antenatal visit after 21 week of gestation (Figure 10). The gestational age of women was measured from the last menstrual period in 74% and by uterine height in 26%, of women.

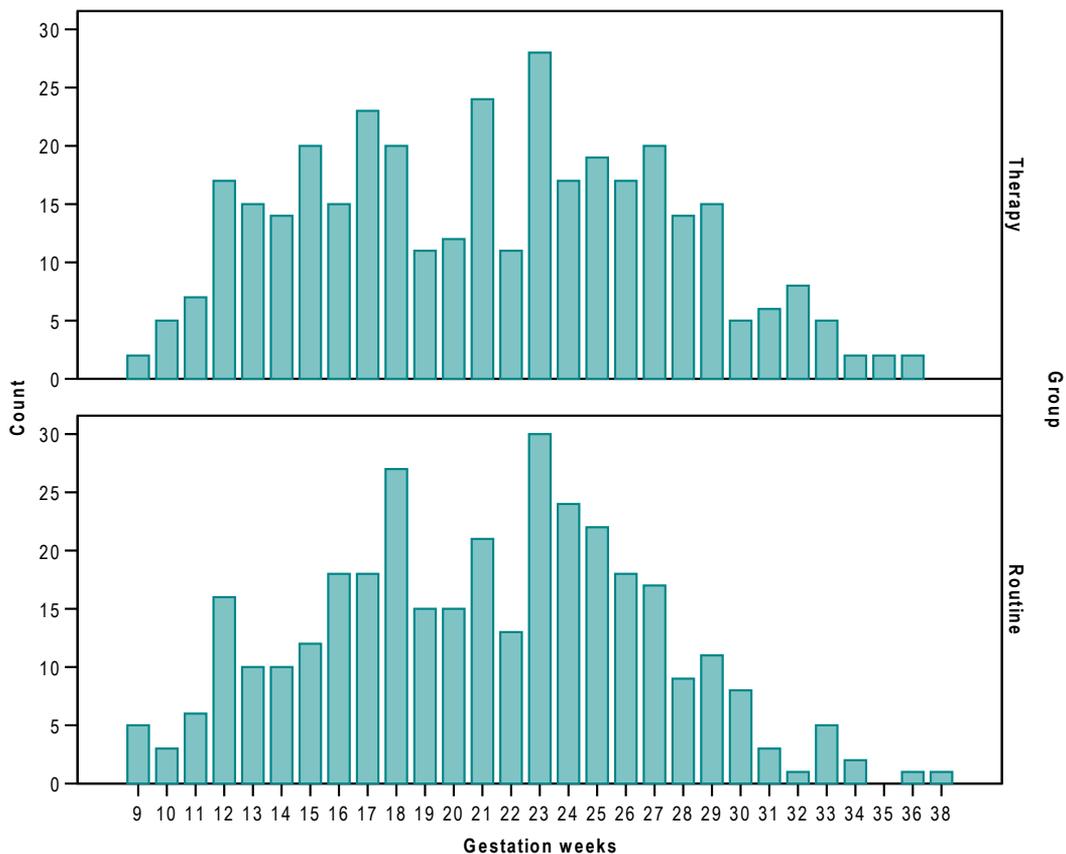


FIGURE 10. Gestation weeks at first antenatal visit by group

This figure shows the number of women coming back for follow up visits until April 2007. The numbers are similar in both groups (Figure 11).

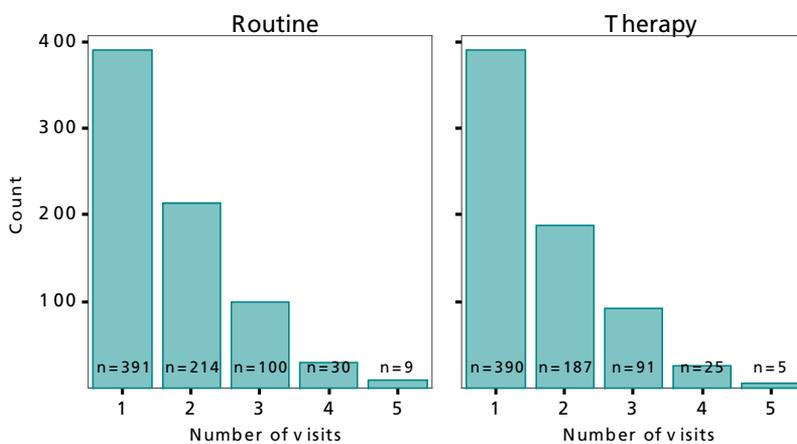


FIGURE 11. Subsequent antenatal visits, by April 2007

Mean number of antenatal visits from first visit to delivery among women who had given birth at the health centre or the reference hospital of Mavalane (134 deliveries). The average number of antenatal visits attended by women who during the pilot study had given birth was 2,4 visits (Table 2). Deliveries that occurred in the central hospital are not included because the study group was awaiting authorization to access to the registers in the central hospital.

TABLE 2. Number of antenatal visits during pregnancy

		Total	Routine	Therapy
N	Valid	134	62	72
	Missing	0	0	0
Mean		2.40	2.50	2.31
Median		2	2	2
Minimum		1	1	1
Maximum		5	5	5

4.5 Haemoglobin measurements with HemoCue

Haemoglobin level was measured in total of 388 women in the therapy group, at the first antenatal visit (Figure 12).

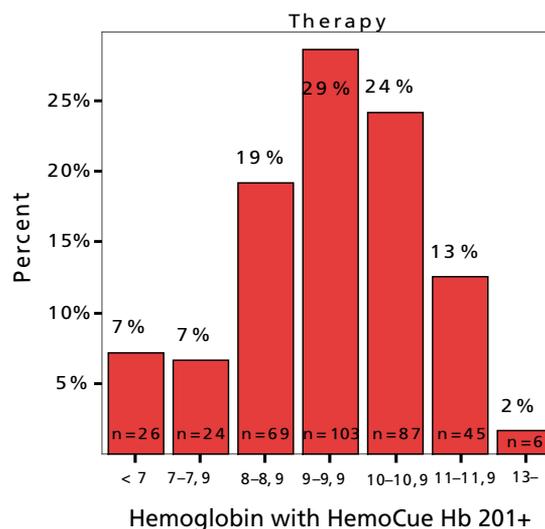


FIGURE 12. Haemoglobin levels of women in the therapy group on first antenatal visit

Haemoglobin was routinely solicited on the first visit from all women. In practice this means that after the antenatal consultation women were asked to go to the laboratory for blood tests, some women went and some women did not. The number of women from whom the haemoglobin measurement of the laboratory was available on the second antenatal visit was n=444, which is equivalent to 57% (Table 3). The haemoglobin result of the laboratory measurement was available on the second antenatal visit for the study nurses, the measurement was done at some point

between the first and second antenatal visit. The laboratory result was copied from the pre-natal card to the data collection form on the second visit.

TABLE 3. Haemoglobin compared between HemoCue and Lovibond

		HemoCue Therapy group	Lovibond
N*	Valid	388	444
Mean		9.5	11.7
Std. Deviation		1.6	0.5
Minimum		4.1	8.0
Maximum		15.0	14.5

* Data extracted in July 2007.

The measurements suggest that anaemia prevalence measured with Lovibond is 0.5% and by HemoCue 31%. The mean difference between HemoCue and Lovibond measurements is -2.065 (CI -2.300 to -1.83). The two measurements for haemoglobin gave different values. The measurement with Lovibond® gave consistently higher values than HemoCue.

Haemoglobin colour scale measurements are cheap and a simple means of screening for anaemia, and is suitable for use in developing countries, but it has been criticized for its inaccuracy. The colour comparison comprises of six different shades of red matched to blood with haemoglobin concentrations. The reading of the result is much dependant on the eye of the reader. [3]

Haemoglobin values on first and subsequent visits in the therapy group did not drop below 9,5g/dl (Table 4).

TABLE 4. Haemoglobin with HemoCue at first and subsequent visits

		1st visit	2nd visit	3rd visit	4th visit	5th visit
N	Valid	389	187	91	23	5
	Missing	1	0	0	2	0
Mean		9,5	9,5	9,6	10,2	10,0
Median		9,6	9,5	9,8	10,3	10,0
Minimum		4,0	5,3	5,9	8,4	8,8
Maximum		15,0	13,6	12,40	13,50	11,2

4.6 HIV Infections

HIV prevalence was 16% in the routine group and 18% in the therapy group (Figure 13).

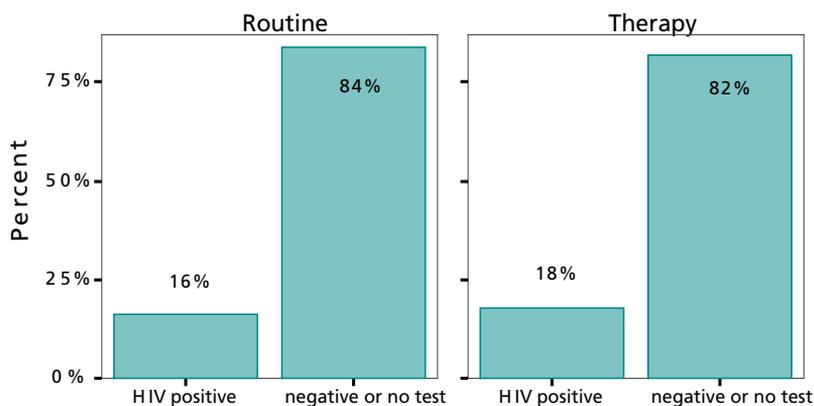


FIGURE 13. Prevalence of HIV by study group (%)

An HIV test (voluntary testing) was done as part of routine antenatal care. Women were counselled and tested for HIV by a separate HIV nurse and they were free to choose if they wanted to be tested. This procedure changed during the pilot, women were no longer counselled by a specialized HIV nurse but by routine MCH nurses. Most women agreed to be tested according to the statistics of the health centre (> 98%). For the study the information on seropositivity was abstracted from the antenatal card, the women were not asked if they were tested and what was the result.

When the pilot started the positive test results were recorded on the top left corner of the antenatal card as a 10 digit numerical code (all women with a numerical code were HIV positive), women with no code were HIV negative or did not have a test done. The numerical coding of the test results was done to ensure confidentiality of the test results.

Once the way of HIV counselling and testing changed, also the recording system changed so that both positive and negative results were recorded on the antenatal card both as different numerical codes. The information we have on HIV status is either positive test result or negative test result/no test.

4.7 Deliveries

In this section the statistical differences in the outcomes are not analyzed or discussed because of the small numbers of deliveries (N=134) that are included in the pilot analysis.

Of women recruited to the pilot 134 deliveries occurred by April 2007. Seventy eight percent took place in 1° de Maio, 17% in Mavalane Hospital and 5 % at home. Home deliveries were recorded in the maternity delivery register when women came with their new born to the health centre after having delivered at home. The MCH nurses took the study card from the women who had delivered at home, inspected the new born and the mother's health status. The information was recorded in the maternity register of births; delivery at home, date of visit to the maternity, weight of new born and health status of the mother. The new born of home deliveries were brought to the health centre or hospital usually on the second or third day after delivery to the health facility. The reason why women saw it necessary to bring the new born to the maternity after giving birth at home was to get a child growth and vaccination card for the baby.

The deliveries that occurred in the central hospital are not included here because the study group does not have nurses at the central hospital to identify women who belong to the study to collect the data. Currently there is no authorization for searching registers at the central hospital. The study group is awaiting for authorization to access the registers in the central hospital.

The deliveries that occur in the central hospital are planned in the future to be traced from the registers in the central hospital.

The differences in the percentages of deliveries in Mavalane and in 1o de Maio is most probably due to the difference in the total number of deliveries by group (Figure 14).

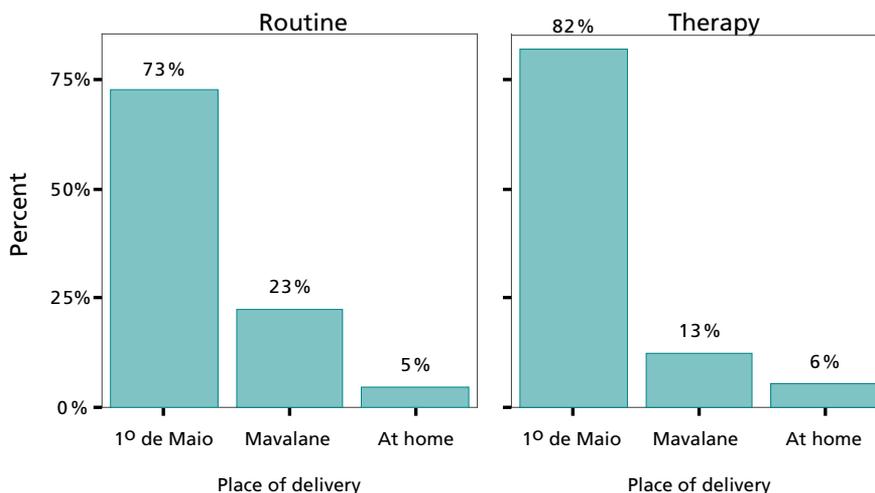


FIGURE 14. Place of delivery by group

The type of delivery by group is shown in Figure 15.

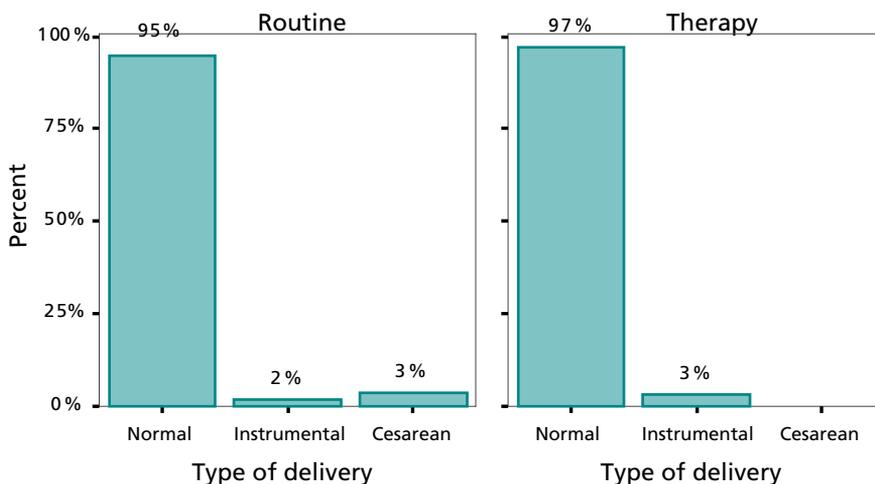


FIGURE 15. Type of delivery by group

The mean gestation weeks at delivery was 36.5 for the routine group and 37.5 for the therapy group (Table 5). Gestation weeks calculated on antenatal visit are not very accurate because women do not often remember/know the time of their last menstruation. Gestation weeks at delivery were calculated by computer from the estimated gestation weeks on the first visit. Gestational age in is rarely recorded on the clinical birth form.

TABLE 5. Gestational age at delivery by group

	Routine	Therapy
Total N	62	72
Missing	14	11
Mean	36.5	37.5
Minimum	23.9	22.7
Maximum	43.4	46.2

TABLE 6. Pre term delivery by group (< 37 weeks)

	Routine	Therapy
Total	48	61
N	23	25
%	47.9	40.9

The mean birth weight was 3 143 grams, the minimum birth weight was 1 000 grams and the maximum 4 000 (Table 7).

TABLE 7. Birth weight by group

		Study group		Total
		Routine	Therapy	
Birth weight	Valid N	61	71	132
	Missing N	1	1	2
	Mean	3 102	3 178	3 143
	Median	3 120	3 160	3 150
	Minimum	1 000	2 400	1 000
	Maximum	3 990	4 000	4 000

Of all of the deliveries (n = 134) 3,8 % of new born were low birth weight (< 2 500 grams). Of these 4 in the routine group and 1 in the therapy group (Table 8).

TABLE 8. Low birth weight by group

		Study group		Total
		Routine	Therapy	
Low birth weight	1 000	1	0	1
	1 980	1	0	1
	2 200	1	0	1
	2 300	1	0	1
	2 400	0	1	1
Total		4	1	5

5 PRACTICAL EXPERIENCES

We would like to present practical experiences from the setting up of the trial and the pilot to share the information from the experiences. Planning and implementing a trial is not an easy task, especially in a developing country it is a challenging and a time consuming process. Problems can rise from small practical issues to bigger issues. During the preparatory phase and the pilot several problems were encountered.

5.1 Constraints during the preparatory phase

- In the preparatory phase, the lack of knowledge of correct procedures for seeking ethical approval for the protocol delayed the process. It was not certain where the protocol should be submitted in Finland (STAKES or a law-based committee) or in Mozambique, at the university's own ethical board or in the ethics committee under the Ministry of Health (CNBS). The preparation and submission of the protocol to the various entities took longer than expected and the starting of the pilot was delayed by about 7 months.
- Folic acid of 1mg, which was used for the therapy group, was not available in the recognized medicine list of Mozambique, and most pharmaceutical companies could only provide 5mg tablets. After negotiations and formal permission from the Ministry of Health, one company was able to import the required 1mg tablets as a special order from India.
- Recruiting personnel for the study was difficult because of general lack of health personnel. All nurses from the nursing institute are pre-placed before finishing their studies. The study ended up using retired nurses which to some extent altered the pace of the work.
- Administrative constraints of the Medical Faculty. In the fear of misuse of funds the procedures for purchase of material was complicated and time consuming. This will also be a problem in the future but to a lesser extent because most material for the entire trial has been bought.

5.2 Constraints during the pilot implementation phase

- Lack of iron tablets in the existing antenatal system was experienced several times. To solve the problem the project acquired a stock of iron tablets.
- Lack of material to be found in Maputo, used for the study. Alcohol for disinfectant was difficult to get hold of, yellow and pink paper for info leaflets and study cards was also difficult to find. Some material was bought in South Africa. Most of the material needed is now bought and it will not be a problem in the future.
- Construction work was ongoing in the pilot health centre and this caused a lack of physical space and disturbed the information sessions by noise, resulting in poor hearing during collective and individual information sessions. Due to construction work study nurses moved their physical place frequently, this created misunderstandings. Women not attending the study nurse after antenatal consultations because they did not know where to localize her. The construction work is still ongoing and will be affecting the study in the future as well.
- Routine nurses work load is big and extra work is not welcomed. In the beginning this influenced the routine nurses' attitude towards the study when there was fear of generating extra work. Negotiations are ongoing to pay the routine nurses monthly incentives for their collaboration.

- Transport for the supervision of activities in the health centre was a regular problem for the local coordinator and field assistant. The use of personal car to visit the study sites was not a well thought option. In the future when the study sites do not need very frequent monitoring, using a personal car and the payment of transport incentive will solve the problem.
- Study nurses complained about full public transport and to avoid the overloaded minibuses (chapas) they left from home at 5.30 am which made their working days long.

5.3 Strengths

- Having older, retired nurses to recruit women for the study was seen as positive by study participants; this was believed to influence positively in the participation rate and the acceptance to participate in the study. Women believed that older nurses were more experienced and they were more trusted.
- Study nurses were hard working and did a very careful job with the data collection.
- Women were in general eager to participate in the study and there were only a few refusals
- Women came back for subsequent visits which was important and some women even after having given birth came to present their babies to the study nurses as the “iron study baby”, this demonstrated satisfaction with the study
- Routine nurses from the health centre received the study group well and were satisfied when the study did not cause extra work for them.

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