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## Research

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# Effectiveness of preoperative bath using Chloroxylonol antiseptic soap on the incidence of post emergency Cesarean section surgical site infection at Mbarara Regional Referral hospital, Uganda: a Randomized Controlled trial

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## **Abstract**

**Introduction:** Surgical Site Infections (SSIs) are infections that occur at or near the surgical incision within 30 days of the surgery. SSIs are the commonest form of hospital acquired infections in sub Saharan Africa with estimates between 15%-45%. Cesarean section (CS) is the single most important risk factor for postpartum infections, carrying a 5 to 20-fold increase in the risk of developing sepsis, with an even higher risk when the operation is an emergency. In sub Saharan Africa, the leading cause of maternal mortality is puerperal sepsis. There is a need for simple interventions that can reduce this burden of SSI in the limited resource settings. Therefore, the purpose of this study was to measure the effectiveness of chloroxylenol in reducing the incidence of post Cesarean section surgical site infections at Mbarara Regional Referral Hospital (MRRH).

**Methods:** We conducted a single blinded randomized controlled trial at MRRH maternity ward in which women due for CS were randomized into either control or intervention arms. The intervention was a complete body bath with chloroxylenol antiseptic soap before the operation, while the control arm study participants received a standard pre-operative preparation procedures according to the existing ward protocol. All participants were followed up for 30 days and assessed using a standard SSI screening tool.

**Results:** Ninety-six women were randomized, and 48 were assigned to either arm. The overall incidence of SSI was 30.21%. The incidence of SSI was significantly lower in the intervention compared to the control arm, at 6.25% in the intervention arm versus 54.17% in the control arm ( $p$  value $<0.001$ ). Chloroxylenol bath was protective of SSI with a 90% risk reduction for SSI (95% confidence interval of 67% – 97%).

**Conclusion:** A preoperative bath with chloroxylenol for pregnant mothers is associated with a significantly lower risk of post Cesarean section surgical site infections. Health facilities with a high burden of post SSI should consider adding this simple and effective intervention to the existing infection prevention measures. **Clinical Trials.gov registration (NCT03544710).**

**Keywords:** Incidence, Surgical site infection, Chloroxylenol, Uganda, Emergency Cesarean section

## **Plain English summary**

Infections of the surgical site are infections that occur at or near the surgical incision within 30 days of the surgery. Cesarean delivery is the single most important risk factor for postpartum infections, with a 5 to 20 increased risk of developing infection, with an even higher risk when the operation is an emergency. In sub Saharan Africa, the leading cause of maternal deaths is post-delivery infection. There is a need for simple interventions that can reduce the burden of post-delivery infections in the limited resource settings. We thus set out to conduct a study to measure how effective chloroxylenol is in reducing post-Cesarean delivery infections at Mbarara Hospital. We compared two groups of women going for Cesarean delivery. In one of the group of 48 participants, women had a complete body bath with chloroxylenol antiseptic soap before the operation while in the other group of 48 participants, women received what is standard preparation which had no body bath before the operation. All these women were followed up after discharge from hospital to ascertain whether they developed post-Cesarean delivery infection. The follow up was up to 30 days post-surgery. The result was that 3 women out of every 10 women had post-delivery infection and the infection rates were lower in the group that had had a complete body bath. It was therefore concluded that a preoperative bath with chloroxylenol for pregnant mothers is associated with a significantly lower risk of post Cesarean section surgical site infections.

**INTRODUCTION:** Surgical site infections (SSI) are infections that occur at a wound following an invasive surgical procedure. The United States Center for Disease Control and Prevention (CDC, 2013) defines SSIs as infections related to the surgical procedure and occur at or near the surgical incision within 30 days of the surgery. Surgical site infections are the commonest hospital acquired infections in sub Saharan Africa (Rothe et al., 2013) with estimates of about 15%-45% (Arabshahi and Koochpayezade, 2006, Mangram et al., 1999) . The incidence of SSIs in the middle and high income settings is much lower and ranges between 1.8-5.5% (ter Gunne and Cohen, 2009, Astagneau and L'hériveau, 2010) while that in low income countries is as high as 45% (Allegranzi et al., 2011).

Cesarean delivery is the single-most important risk factor for postpartum pregnancy-associated infections carrying a 5 to 20-fold increase in the risk of developing sepsis (Smaill and Grivell, 2014). In sub Saharan Africa, surgical site infections remain a substantial cause of morbidity, prolonged hospitalization and mortality. Puerperal sepsis, which is part of the SSI broad spectrum, is the leading cause of maternal mortality at MRRH (Ngonzi et al., 2016). Emergency Cesarean sections have been associated with a higher risk of infections than elective Cesarean sections (Beattie et al., 1994).

Despite several interventions to reduce postpartum infections after Cesarean section the burden of SSI remains high (Kassavin et al., 2011). There is a need for cost effective interventions with potential to scale widely, to tackle the challenge of SSI in sub Saharan Africa and other resource limited settings. One such intervention is an antiseptic bath. Chloroxylonol, also known as para-chloro-meta-xylonol, is an antiseptic and disinfectant used for disinfecting skin and surgical instruments. It was first made in 1927 and is on the World Health Organization's Essential Medicines list. It is a common constituent of household products like medicated soap, and antiseptics (Ascenzi, 1995). It works by both disruption of the cell wall and by stopping the function of enzymes (Mahon, 2017) and has a role in ridding the skin of pathogenic organisms.

Preoperative antiseptic bathing reduces skin microbial colony counts and this reduces the risk of wound contamination. There is no conclusive evidence whether the practice has a corresponding protective effect on the incidence of SSIs in a surgical setting (Mangram

et al., 1999). Preoperative bathing of patients is currently not practiced routinely in sub-Saharan Africa and therefore its impact on reducing the burden of SSI is unknown. Therefore, the purpose of this study was to assess whether an antiseptic soap bath of chloroxylenol is associated with reduction in the incidence of surgical site infections among post Cesarean women at a large urban hospital in a resource limited setting.

## **METHODS:**

### **Study site and setting:**

We conducted a randomized controlled single blind trial between November 2017 and February 2018 at the maternity ward of Mbarara Regional Referral Hospital (MRRH), in southwestern Uganda. The Maternity ward has the following units which were included in the study-antenatal ward, labor ward, and postnatal ward. The facility is government owned and also serves as teaching hospital for Mbarara University Medical School and hosts 12,000 deliveries annually with a catchment population of nine million people, largely rural and peri-urban population.

**Standard of care:** All mothers scheduled for Cesarean section are given intravenous prophylactic antibiotics, but it's not a practice for them to have a preoperative bath. Following delivery, and regardless of the mode of delivery, mothers are admitted to the postnatal ward where they are reviewed daily by a physician and given treatment for pain management and for prevention of postpartum infections. The drugs used for post-operative treatment are intravenous antibiotics namely: ceftriaxone, metronidazole and ampicillin while the drugs for pain management include opioids such as pethidine. The physicians manage new patient symptoms as they emerge and appropriately revise their medication as need arises.

**Inclusion and exclusion criteria:** All women delivering by emergency Cesarean section at MRRH were eligible to participate if they had no obvious evidence of infection such as fever, foul-smelling liquor, or those already on antibiotics for reasons other than preoperative prophylaxis. We also excluded women in whom emergency caesarian delivery was expected to occur within less than 30 minutes such as those with fetal distress, obstructed labor, pulsatile cord prolapse, or ruptured uterus. We also excluded

women who could not communicate and give information for the study and those who did not have access to an active cell phone contact for purposes of follow up.

**Participant enrollment and randomization:** All women who met the inclusion criteria were consecutively enrolled into the study by the mid wife research assistant, who was not part of the clinical team and study participants were enrolled until the sample size was attained. The research assistant obtained written informed consent from each study participant and collected demographic and baseline clinical information using a study tool. Informed consent for the surgery was obtained separately from that for the research. The study participants were then randomly assigned to either the intervention or the control arm based by picking a sealed envelope from the randomization basket. The group of assignment was determined when the envelope was opened and once opened, there was no replacement.

**Routine care for all caesarian mothers:** All mothers had an intravenous cannula inserted and were administered Ampicillin 2g intravenously for prophylaxis. The women had a blood sample of 3mls drawn for blood grouping and cross matching to secure a unit of blood in case they needed a transfusion. Mothers then received 1 liter of intravenous normal saline, and had a urethral catheter placed for drainage of urine.

**Intervention:** Women randomized to the intervention arm received a tablet of soap containing chloroxylenol antiseptic and they were asked to use the soap to take a full body bath on the admission ward. The research assistant provided warm water to the participants and she further supervised the bathing process to ensure that the entire body, apart from the hair, had been washed. The bathing process on average lasted twenty minutes. Following the bath, the participants were dressed in a clean theatre gown, and then received pre-operative preparation normally accorded to all mothers scheduled for Caesarean section as a standard of care.

**Control arm:** Participants randomized to the control group received the routine pre-operative procedures provided to all emergency caesarian section patients as a standard of care. The routine pre-operative care included establishing an intravenous cannula, intravenous normal saline fluids for preloading, intravenous pre-operative antibiotics (ampicillin), informed written consent, blood for grouping and cross matching plus



informing theatre staff. If a participant in the control arm requested to have a bath before the operation, they were provided with warm water and a non-medicated soap for their bath. Participants who had a bath with non-medicated soap were still eligible to remain in the control arm.

**Follow-up procedures:** The research assistant and the ward clinical team in charge of assessment of the patients for clinical outcomes were blinded to the randomization arm of the patients. The patient assessments were conducted daily until the date of discharge. The research assistant used the findings of the ward clinical team to complete the case report forms for the study participants. The ward clinical team asked questions and performed clinical examinations on the participant to assess for evidence of SSI. Participants were asked whether they had severe pain at the incision site. Pain was regarded as severe if the participant reported that the pain stopped her from moving out of bed. Axillary body temperature, radial pulse rate and respiratory rate were measured twice daily. The ward clinical team examined the incision site and assessed for induration (edema or erythema), purulent discharge, and severe tenderness as evidenced by guarding. The temperature of the skin around the incision site was examined and compared with that of the skin remote from the incision site to determine whether it was warmer around the incision site. A ward clinical team member asked to examine the vaginal pad in order to assess the nature of the per-vaginal discharge.

The decision to discharge the participants from hospital was made by the ward clinical team. Upon discharge from the hospital, the participant was given an appointment to return on the 7<sup>th</sup> post-operative day for follow up. At this visit, they were asked questions and examined, all following the same procedures as those during their admission to evaluate for evidence of SSI. If a participant failed to turn-up for the appointment, they were contacted on phone by a member of the research team and requested to return and for those who were not able, the research assistant would locate their residence and travel there for the follow up.

At the 30<sup>th</sup> day post-operative, the research assistant followed up the participants through a telephone call and asked them questions about how their health had been from their last visit (7<sup>th</sup> post-operative day) to the current date. Participants were asked questions

about feeling feverish, severe lower abdominal pain, or any discharge from the incision site, or a foul-smelling per-vaginal discharge, or if they had sought medical care from a facility due to issues related to operation site since their last hospital visit. Participants had been given a hotline to call a member of the research team in case they had a medical problem. All participants that met the criteria of SSI at any time were referred to the existing clinical care system in the department of Obstetrics and Gynecology at Mbarara Regional Referral Hospital for treatment.

**Measurements:** Data were collected on socio-demographics like age in years, parity, address or village of residence, marital status, educational level, occupation, income, and partner's factors including income, occupation, and education level. We collected information on obstetric care factors like indication for the Cesarean section, stage of labor, status of membranes, number of digital vaginal examinations done, prophylactic antibiotics (whether given or not, which one given, and how long before the incision was it given), the cadre of the primary surgeon, the cadre of the assistant surgeon, time of the day when the operation was done, length of the operation, skin closure technique, suture material used for closure, a completely filled WHO surgical checklist. We also collected data on history of medical conditions like diabetes mellitus, sexually transmitted diseases, HIV, and urinary tract infections.

Primary study endpoint:

The primary outcome was surgical site infection following Caesarean section delivery, defined as infection involving skin, subcutaneous tissue, fascial layer, muscle or organs, occurring with at least one of the following; 1) Purulent discharge from the incision site 2) Spontaneous wound dehiscence 3) Surgeon deliberately opens the wound when the patient has at least one of the following; pain or tenderness, localized swelling or induration, redness, or heat 4) An abscess or evidence of infection involving the deep incision or organ space found on direct examination, during reoperation, or by ultrasonography 5) Diagnosis of surgical site infection by attending surgeon.

**Sample size calculation:**

We conducted sample size calculations for randomized controlled trials using the Kelsey et al formula (Kelsey et al., 1996). We estimated the incidence of SSI to be 26%

(Arabshahi and Koohpayezade, 2006) and assumed that administration of the pre-CS bath would result in a 75% reduction in incidence of SSI. A sample size of 48 participants per arm would detect such a difference or more with 80% power, using a 5% level of significance.

### **Data Management and Analysis:**

We examined the completed case report forms, screening tools and phone call interview sheets on each day for completeness before storage in a lockable cabinet. The data were then entered into a Research Electronic Data Capture (REDCap) database (Harris et al., 2009) and later exported to STATA 13.0 software for cleaning and analysis.

In the analysis, baseline characteristics were stratified by intervention arm and summarized using proportions for categorical variables and Chi-square tests were performed to examine whether balance for prognostic factors in the two arms was achieved during the randomization process. Fisher's exact test was used in case the expected numbers in the cells was less than 5. Continuous variables like age, income, length of operation and others, were categorized and analyzed as other categorical variables. The statistical tests were performed at a level of significance of 0.05.

Our aim was to present the intention to treat analysis as the primary analysis. We compared the incidence proportion of SSI in the intervention and control group, and calculated the relative risk (RR) for SSI in the intervention and control arms. We calculated the risk reduction for SSI in the intervention as  $1 - \text{RR}$  and computed the 95% confidence interval.

## **RESULTS:**

**Participants recruitment process:** We screened 373 patients and 277 participants were excluded due to various reasons as follows: 113 participants had indications for Cesarean section that necessitated the operation to be done within 30 minutes, 41 participants were already on antibiotics, while 124 participants did not have access to a working telephone, and 39 participants declined taking part in the study. All participants recruited were included in the final analysis and no participant was lost to follow-up, and neither did any participant withdraw after recruitment. Also, no participant switched from the randomization arm to which they had been assigned to.

## **PARTICIPANTS BASELINE CHARACTERISTICS**

**Socio-demographics of study participants:** Generally, there was a uniform distribution for the majority of the participants' socio-demographics among the two study groups. Majority of the participants reported having supportive partners. Majority of the participants had close relatives (mother, sister and husband) as the primary care taker in hospital.

**Obstetric care factors and medical factors of study participants:** Generally, participants did not differ in their obstetric care factors across the two study groups. Uneven distribution of participants among the two groups was however observed for type of Cesarean section done and number of digital vaginal examinations done before the operation with p-values of 0.011 and 0.007 respectively. Majority of the participants were in active stage of labor. Junior residents were the leading primary surgeons whereas intern doctors assisted in most of the operations. Majority of the participants had their skin closed with the non-absorbable suture.

## **Incidence of Surgical Site Infection in the study groups**

Table 3 shows that the incidence of SSI was much higher among the mothers who did not have a preoperative bath compared with those who had a preoperative bath with chloroxylenol, with incidence rates of 54.17% and 6.25% respectively. Thus, preoperative bathing with chloroxylenol gives an absolute risk reduction or risk difference of getting SSI of 47.92%, and a relative risk reduction of 88.5%.

**Obstetric care factors associated with post Cesarean section surgical site infection among all study participants:** Preoperative bathing was found to be the only significant obstetric care factor with an unadjusted risk ratio of 0.1 at a 95% confidence interval of [0.04-0.36] and a level of significance of p-value <0.001. No medical factor was found to be significant for surgical site infection. After adjusting for number of VE's done (Table 4), pre-operative baths were associated with a 90% reduction in incidence of SSI (95% CI 67%-97%).

**Adverse events:** We did not receive complaints of allergic reactions, irritations or record any dermatitis or other adverse effects associated with the use of the soap.

## **Discussion**

We have demonstrated that a simple and inexpensive intervention can reduce the incidence of post Cesarean section surgical site infection at a health facility in a resource limited setting. Our data show that preoperative bath with chloroxylenol provides risk reduction of more than 80% in the incidence of SSI, signifying the strength and potential of this simple intervention. Overall, the incidence of SSI among post cesarean mothers at our hospital is very high, at over 50% based on the data from the control group. The evidence provides a strong tool to potentially reduce SSI in similar settings in sub Saharan Africa, where there is a high volume of Cesarean delivery with a high incidence of SSI, such as Uganda.

Our study shows that implementation of pre-operative births is feasible in a busy maternity ward, and therefore the application should be simpler to implement in health facilities with even less patient traffic. With at least 30 deliveries per day of which 40% are cesarean, the maternity unit is extremely busy. In this study, we included only those mothers who had a least 30 minutes to their CS, and therefore some mothers who needed the bath did not receive it due to the urgency for them to get to theatre for their CS. From our experience, the average duration of the bath was 20 minutes, and therefore for future implementation purposes, this could be shortened to allow even those mothers with less than 30minutes to their operation to have it. An alternative approach is to have shower rooms in the operating theater that would enable mothers to be wheeled directly from shower to table, hence saving valuable time in transit. Future studies that seek to assess

implementation science of per-operative baths should consider conducting studies of acceptability of this intervention at maternity units. Midwives and obstetricians will need to buy into this intervention for the implementation to be successful.

Chloroxylenol is an inexpensive antiseptic that is in common use in hospital settings and outside hospital setting in household items such as antibacterial soaps. It is an effective component of antibacterial soaps and has demonstrated a significant reduction in fecal coliforms in handwashing experiments (Pérez-Garza et al., 2017). Given its antibacterial properties, there are concerns about potential contribution to the emergence of bacterial resistance if the use is widespread, especially outside clinical settings. And the widespread use is likely to grow following a ban on triclosan and triclocarban in antibacterial soaps by the Food and Drug Administration of the United States (Rundle et al., 2019). Antibacterial soaps are not widely used in households in sub-Saharan Africa, and therefore the potential emergence of bacterial resistance is unlikely to be a challenge in foreseeable future. Also of concern is the possible dermatitis associated with antibacterial soaps. Certain fragrances in these soaps are associated with contact dermatitis (Schlarbaum and Hylwa, 2019). In our study, we did not record any dermatitis associated with the use of the soap. However, we recommend that such adverse effects should be evaluated if this intervention

The burden of postpartum infections at our study site and many settings in sub-Saharan Africa is very variable but mostly high (Sway et al., 2019, Chu et al., 2015, Arabshahi and Koochpayezade, 2006, Mangram et al., 1999). Previous studies have shown that mothers who undergo emergency cesarean sections are at a higher risk for SSI compared to those undergoing elective procedures (Yang and Sun, 2017). Mothers that need emergency CS are usually referred from peripheral rural sites, have travelled long distances, not prepared for surgery, with some mothers involved in farming, brought to the hospital straight from their gardens, exposing them to high risk for infections. These infections contribute significantly to adverse maternal outcomes (Wendmagegn et al., 2018). Data from one of our previous studies and many others have shown that puerperal sepsis is the leading cause of maternal mortality in the hospital (Ngonzi et al., 2016, Majangara et

al., 2018). Finding such a high incidence of SSI among post emergency Cesarean section mothers only confirms the burden as being huge, and one that needs extra attention.

Research conducted elsewhere shows incidence rates for SSI lower than what we found in our study. Jimma University Teaching Hospital, Ethiopia, whose setting is very similar to that of Mbarara Regional Referral Hospital, found the post Cesarean section SSI rate to be 11.4% (Amenu et al., 2011). The study found a lower incidence probably because they followed up all post Cesarean section mothers, including elective cesarean sections, who are at a lower risk for SSI. Similarly, studies done in Bugando Medical Centre, Mwanza, and in Kiambu District hospital in Kenya had lower incidence rates of SSIs of 10.9% and 19% respectively probably because both studies enrolled elective and emergency Cesarean section mothers (Mpogoro et al., 2014, Koigi-Kamau et al., 2005). Our study enrolled only emergency Cesarean section mothers. It is well known that emergency Cesarean sections have higher rates of SSI than elective Cesarean sections.

To the best of our knowledge, this is the first study to evaluate the effectiveness of this simple and inexpensive intervention on SSI in sub Saharan Africa. We found a study that examined the effect of pre-operative baths on SSI (Allegranzi et al., 2018), and found there was a significant benefit in the intervention. However, this study was significantly different from our study in several ways. First, this study was conducted among a general surgical population. Second, the study was a multi-modal approach with several interventions embedded in the design in addition to the pre-operative baths. These fundamental differences make it impossible to make any comparisons between the two studies. However, both studies share the common finding that pre-operative baths can significantly reduce SSI.

**Conclusions:** In conclusion, the results of this study suggest that pre-operative bathing with chloroxylenol soap greatly reduces the risk of post Cesarean section surgical site infections. In a tertiary hospital which has a high burden of postpartum infections, adding this cheap, yet efficacious practice on the already existing infection prevention measures will contribute to a big reduction on the burden. Even though the study was done among mothers scheduled for emergency Cesarean sections, the practice may have benefits

among elective operations as well. However, future studies may be necessary to evaluate the benefits among these patients.

The strengths to our study is that we conducted a randomized controlled trial, and complete follow-up of all participants to 30 days, with no loss to follow up. Second, is that we evaluated a simple and inexpensive intervention, is easy to implement and therefore has potential for wide scale impact. And lastly, to the best of our knowledge, this is the first study of its kind to evaluate this intervention in a randomized controlled study among cesarean mothers. A recent multi-centric study (Pérez-Garza et al., 2017, Allegranzi et al., 2018) that examined the impact of pre-operative baths, was done among a general surgical population and in addition, the baths were not chlorhexidine, and also this study had a multi-modal intervention approach with a before-after design, and not a randomized controlled design.

Our study has some potential weaknesses. First, we were not able to have all the mothers return to the clinic to have an objective clinical assessment. Instead, we followed up the mothers via phone and therefore relied on the self-reports. Second, we did not culture the micro-organisms to identify the cause of the SSI. However, other studies in the region have been done and the common organisms that cause SSI and the drug sensitivity pattern have been studied and are now known (Hope et al., 2019) (George et al., 2018).

**Conflict of interest:** We declare no conflict of interest and no financial assistance, or any incentive obtained from any corporation with commercial interests in the investigational product.

## **Declarations**

**Ethics approval:** The study and enrollment procedures were approved by the Mbarara University of Science and Technology Research ethics committee (08/08-17), the trial was registered at the portal Clinical Trials.gov (NCT03544710) and received the final approval from the Uganda National Council of Science and Technology (HS/215ES).

**Availability of data and materials:** The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.



Consent for publication: Written informed consent for publication was obtained from the participants.

**Competing interests:** The authors declare no competing financial and non-financial interests.

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**Authors' contributions:** HL conceived the idea, carried out the research, analyzed the data and wrote the manuscript; JN participated in the data collection, data analysis and manuscript write-up; RK participated in data collection and critical manuscript revisions; DM participated in data collection and critical manuscript revisions; HM participated in data collection and critical manuscript revisions; BM participated in data collection and critical manuscript revisions; AB participated in data analysis and critical manuscript revisions; AM participated in data analysis and critical manuscript revisions; JJL participated in data analysis and critical manuscript revisions; FB participated in data analysis and critical manuscript revisions, MK participated in data analysis and critical manuscript revisions; RM participated in data analysis and critical manuscript revisions; JM participated in data analysis and critical manuscript revision; FB participated in data analysis and critical manuscript revisions.

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**List of abbreviations:**

CDC (Center for Disease Control and Prevention)

CS (Cesarean section)

HIV (Human Immunodeficiency Virus)

MRRH (Mbarara Regional Referral Hospital)

REDCap (Research Electronic Data Capture)

SSI (Surgical Site Infection)

RR (Relative risk)

VE (Vaginal examination)

UGX (Uganda shillings)

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# Figures

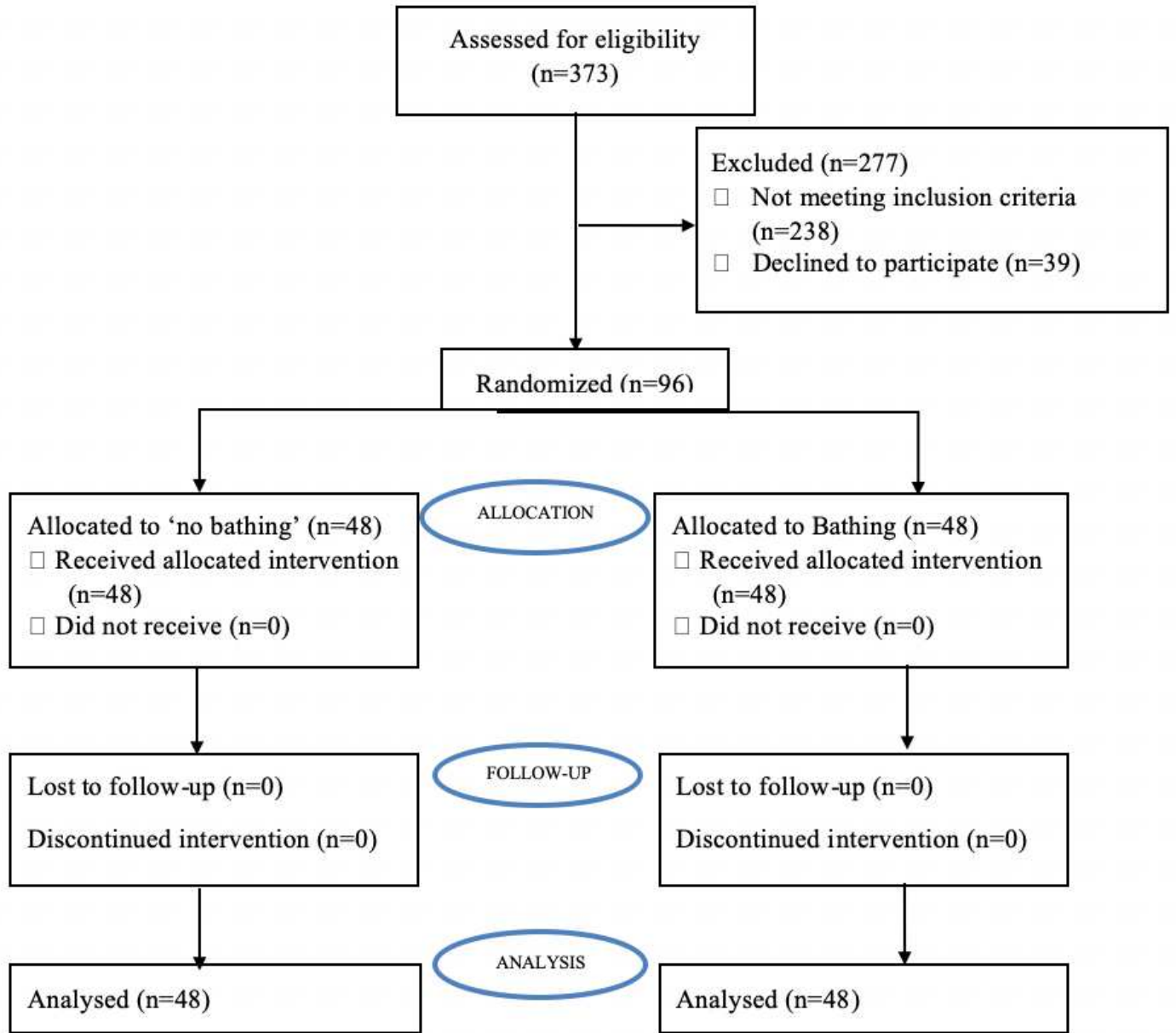


Figure 1

Consort diagram showing the recruitment process