A randomized controlled trial: The efficacy of mother’s involvement to serve comfort on infants during the intramuscular immunization procedure

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Abstract. Background: A Diphtheria Pertussis Tetanus immunization often causes trauma in infants because it is done by intramuscular injection. Purpose: The aim of this study is to determine the effect of facilitated tucking by mother combined with sitting up position on the level of pain when infants receive intramuscular immunization. Method: A randomized controlled trial design with post-test equivalent group technique was used. This study was registered in ISRCTN Register with study ID ISRCTN43763425. Three groups (intervention by mothers, intervention by health worker, and control group) were randomly selected, with each consisting of 16 infants. Results: Data were analyzed using the Kruskal Wallis test with a ρ value=0.008 (< 0.05). The result of the analysis conducted by post hoc Mann-Whitney test revealed that (1) intervention by mother vs intervention by health worker group have a ρ value=0.028 (<0.05); (2) intervention by mother vs control group have a ρ value=0.604; and (3) intervention by health workers vs control group have a ρ value=0.003. Conclusion: There was a significant difference in the level of infant pain between intervention by mother vs intervention by health worker, and intervention by health worker vs control group. Recommendation: It is recommended that facilitated tucking by mother combined with sitting up position should be used in infant pain management during intramuscular immunization.

Keywords: facilitated tucking, , infant, maternal involvement, pain, randomized controlled trial

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Introduction

The Indonesian government established a complete basic immunization that must be given to infants up to 9 months. Three of these are given by injection and observed to be causing pain in the infants. Data on Bacillus Calmett Guirnett (BCG), Diphtheria Pertussis Tetanus (DPT), and Hepatitis B from the Indonesia Health Profile 2016 showed that the country has achieved the 2016 strategic plan target of 91.5%. In the same year, basic immunization was 91.58% with 12 provinces achieving the target and this was greater than 86.54% recorded in 2015 (Depkes RI, 2016).

This is in line with the information from Banggetayu Community Health Center that the level of maternal compliance to provide immunization to their infant was quite high. A preliminary study conducted showed that majority of the immunized infants were accompanied by their own mothers. The majority of Community Health Centers have not implemented interventions in the handling of pain responses in children immunized.

Pain due to injection of immunization if not controlled properly has a negative impact such as crying and fear on the emotional aspects of the infant. Physical and psychological effects, such as rapid and shallow breathing, and behavioral disturbance can also occur if the pain was not immediately treated. Therefore, as health workers, especially nurses who

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are in primary health care services, there is a need to prepare effective pain management for infants when getting immunization injections (Twycross, Dowden, & Bruce, 2009).

Local midwives have been trying to come up with an effective method of tackling this. However, comfort has been observed to be very important in the development of trust for infants while growing up. One element of this can be found in the quality of the relationship between them and the type of care their parents provide for them (Wilson & Hockenberry, 2012).

This can be improved through the active role of parents during immunization schedule which is in accordance with the principles of child nursing, namely Family Centered Care (FCC). Parental involvement in infant care can increase their comfort and also serve as a form of intervention that can improve the quality of mother-infant relationship (Ball, Bindler, Cowen, & Shaw, 2017). Facilitated tucking, for example, is an effective and safe intervention that is often forgotten by health workers. This is done by facilitating folding or physiological flexion of the infant (Kucukoglu et al., 2015). It is one of the non-pharmacological methods that can be carried out independently by health workers or mothers who accompany infants when they are given immunization injections. This method has been observed to be more effective if combined with another non-pharmacological pain management method (Gomella, Cunningham, & Eyal, 2013). According to previous research, sitting up position was more effective then supine position (Lacey, Finkelstein, & Thygeson, 2008). Research comparing the facilitated tucking combined with sitting up position by mothers, health workers, and sitting up position is still limited. Therefore, this study was aimed at knowing if facilitated tucking by mother combined with sitting up position can influence the level of pain of an infant during immunization injections.

Methods

This is a randomized controlled trial design with post-test equivalent group technique was used. This study was registered in ISRCTN Register with study ID ISRCTN43763425. Facilitated tucking combined with sitting up position were the interventions employed and three groups (a) intervention by mother group; (b) intervention by health workers group; (c) control group were created. In the control group, infants were just in sitting up position through the help of their mother during immunization.

Posttest was conducted through the evaluation of infant pain level using FLACC by a child nursing specialist. An assessment was done by looking at the video recorded when the injection was given. Furthermore, before the intervention, mothers and health workers were made to wear the same clothes in order to ensure that the nurse specialist did not know who was performing the intervention and to avoid bias.

The population of this study was infants aged 2-12 months that underwent DPT immunization in Bangetayu Community Health Center on August 2018. The minimum sample in each group was 14 respondents, and in anticipation of the possibility of a dropout, corrections were made by adding 10% of the total sample making it a total of 16 respondents (Polit & Beck, 2017). Consecutive sampling through inclusion and exclusion criteria was used (Dahlan, 2014; Grove & Gray, 2019). Data collection tools used include questionnaire sheets to identify the demographic characteristics of respondents, and observation sheets to assess the FLACC pain scale. The results of the research was carried out in consultation with statisticians and child nursing specialist.

![Flow diagram showing random allocation of participants, exclusions, follow-up and analysis groups.](#)
participants received sitting up position by mother when intramuscular injection. Intervention by mother = participants received facilitated tucking combined with sitting up position by mother when intramuscular injection. Intervention by health worker = participants received facilitated tucking combined with sitting up position by healthworker when intramuscular injection.

**Results**

The demographic characteristics of the respondents are as shown in table 1. The median age of the youngest infant was found in the control group to be 2.5 months. While the median value for the lowest level of pain was in the intervention group by mother, which is 3 (mild pain).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
<th>Median (Minimum–Maximum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant’s age by months</td>
<td>Intervention by mother (N=16)</td>
<td>4 (2 - 6)</td>
</tr>
<tr>
<td></td>
<td>Intervention by health worker (N=16)</td>
<td>4 (2 - 8)</td>
</tr>
<tr>
<td></td>
<td>Control (N=15)</td>
<td>3 (2 - 5)</td>
</tr>
<tr>
<td>Mother’s age by year</td>
<td>Intervention by mother (N=16)</td>
<td>31.5 (21-40)</td>
</tr>
<tr>
<td></td>
<td>Intervention by health worker (N=16)</td>
<td>28.5 (22-39)</td>
</tr>
<tr>
<td></td>
<td>Control (N=15)</td>
<td>30 (22-42)</td>
</tr>
<tr>
<td>Pain level</td>
<td>Intervention by mother (N=16)</td>
<td>5 (4 - 9)</td>
</tr>
<tr>
<td></td>
<td>Intervention by health worker (N=16)</td>
<td>6.5 (5 - 10)</td>
</tr>
<tr>
<td></td>
<td>Control (N=15)</td>
<td>5 (5 - 7)</td>
</tr>
</tbody>
</table>

The results of the differences in pain levels were obtained through bivariate analysis conducted in several stages. Steps that were taken include (a) data normality test, (b) data transformation, (c) Kruskal-Wallis test because the result of normality test on data transformation was ρ value=0.007, (d) and the post hoc analysis using Mann-Whitney test.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Median (Minimum–Maximum)</th>
<th>ρ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain level</td>
<td>Intervention by mother (N=16)</td>
<td>5 (4 - 9)</td>
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<tr>
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<td>Intervention by health worker (N=16)</td>
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<tr>
<td></td>
<td>Control (N=15)</td>
<td>5 (5 - 7)</td>
</tr>
</tbody>
</table>

Kruskal-Wallis test. Post hoc Mann-Whitney test: Intervention by mother Vs Intervention by health worker ρ=0,028; Intervention by mother Vs Control ρ=0,604; Intervention by health worker Vs Control ρ=0,003.

The data in table 2 showed that the ρ value < 0.05 which means that there were differences at least between two groups. The post hoc Mann-Whitney test revealed that the differences were actually on two groups and they include intervention by mother vs by health worker group and intervention by health worker vs control group.

**Discussions**

Controlling pain in newborns is beneficial to the enhancement of their physiological, behavioral and hormonal responses (Witt, Coynor, Edwards, & Bradshaw, 2016). Pain level at the intervention by mother group was at the lowest range by being mild. Whereas in the intervention by health worker and control groups, moderate pain was observed. Therefore, mothers have to recognize that infants need their comfort and ensure that they provide it (Khasanah, Rustina, & Syahreni, 2015). In this case, they can achieve this by looking at the expression on an infant’s face.

Previous studies that used facilitated tucking as an intervention on premature infants showed that it is quite effective against alleviating the level of pain on premature infants (Alinejad-Naeini, Mohagheghi, Peyrovi, & Mehran, 2014; Khasanah & Rustina, 2017; Lopez et al., 2015; Yin et al., 2014). Additionally, on another study facilitated tucking could reduce duration and frequency of crying during rest times among infants born prematurely (Valizadeh, Gahreman, Ghareshbahi, Jafarabadi, & Farshi, 2018). However, this study is different from previous based on the fact that it was conducted by combining facilitated tucking with sitting up position by mothers and health workers (Fontes, Ribeiro, Dantas, & Ribeiro, 2018).

Facilitated tucking is a non-pharmacological pain management that can help the infant to feel comfortable, calm, save energy, and minimize oxygen consumption. Furthermore, it is a form of developmental care because of the therapeutic
touch it gives to infants when applied. Combining it with sitting up position can increase the comfort of an infant who gets DPT immunization because of the skin to skin contact applied.

The results indicate that there are differences in the level of pain in the group that received intervention by mother vs by health worker. This can be associated with the fact that mothers have a strong bond with their child. In fact, they can identify the infant’s pain especially through crying and changes in expression (Soares et al., 2017). Therefore, mothers can quickly provide comfort to the infant compared to the health worker.

Facilitated tucking by mothers is effective enough to reduce infant’s pain level (Taddio et al., 2018). In accordance with this, this study revealed that the intervention by mother group had the lowest level of pain compared to the others with the level found to be moderate with intervention by health workers. Therefore, this position is effective enough to provide comfort on the infant and much better if given by mothers. Furthermore, multisensory stimulation could be more effective to provide comfort on the infant (Bellieni, Tei, Coccina, & Buonocore, 2012). This research reinforces the importance of a combination of several techniques that can be used by health workers to reduce the level of pain in infants during painful procedures.

No significant differences in pain levels were found between the control and intervention by mother groups. This can be because the position performed by mother in each group and all positions allows therapeutic touch between mother and infant, therefore, the infants are comfortable even before the procedure was carried out. Furthermore, after completing the procedure, the mother can also immediately provide comfort according to the infant’s need through breastfeeding. Based on previous research, breastfeeding is also one of the effective methods of non-pharmacological pain management (Khasanah, Tiara, & Susanto, 2018).

The limitation of this study was that when taking video, the response of children is not focused because it involves the environment, so the next research need to use a special room in conducting immunization procedures. This study uses single blinding RCT method, further research is expected to use double blinding.

**Conclusions**

There were significant differences between the intervention by mother vs by health worker groups; and the intervention by health worker vs control groups on the infant’s pain level during DPT immunization injection procedure. However, it is recommended that facilitated tucking combined with sitting up position should be used to reduce infant’s pain level during any painful procedure. This position is very easy to apply, inexpensive, and provide mother-infant interaction. Therefore, immunization injection procedure, especially at the Community Health Center should be conducted by facilitated tucking combined with sitting up position by mothers.

**Conflict of Interest**

There are no conflict interest on this study. The intervention by facilitated combined sitting up position is very easily applied. But in subsequent implementation depends on the policy of Community Health Centers. In the control group was already used sitting up position, so health workers simply directs mothers to facilitated tucking the infants.

**Acknowledgements**

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**Ethical Consideration**

The ethical clearance of this study encompasses confidentiality, and right to withdraw. Approval was received from Faculty of Nursing Science, Sultan Agung Islamic University Ethics Committee and official permission from Bangetayu Community Health Center where the study was conducted was obtained. Additionally, informed written consent was obtained from each family included in the study.

**References**


