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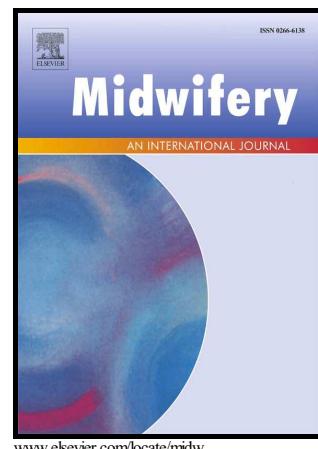
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# Author's Accepted Manuscript

Skin care for healthy babies at term: a systematic review of the evidence

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### Skin care for healthy babies at term: a systematic review of the evidence

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#### Abstract

#### Objectives

To identify what skin practices are important for the protection of baby skin in healthy term babies (0-6 months) and generate evidence-based conclusions to inform health professionals and parents.

#### Design

Eleven databases were searched for all empirical quantitative and qualitative research published between 2000-2015 which explored baby skin care for bathing and cleansing, nappy care, hair and scalp care, management of dry skin or baby massage, for healthy term babies up to 6 months old. Papers not published in English were excluded. A total of 3062 papers were identified. Pairs of

reviewers assessed all citations and extracted data independently. There were 26 included papers: 16 RCTs, 3 non-randomised experimental studies, 1 mixed-methods study and 6 qualitative studies. Primary and secondary outcome measures were analysed using meta-analysis or narrative descriptive statistics. Synthesis of qualitative data was not possible due to disparity of the evidence.

### Findings

From the small numbers of studies with comparable data, there was no evidence of any significant differences between tested wash products and water or tested baby wipes and water. There was some evidence to suggest that daily use of full-body emollient therapy may help to reduce the risk of atopic eczema in high risk babies with a genetic predisposition to eczema; however, the use of olive oil or sunflower oil for baby dry skin may adversely affect skin barrier function. There was no evidence about hair/scalp care or baby massage. Qualitative research indicates that parents and health professionals believe that water alone is best.

### Key conclusions

Meta-analysis was restricted due to the lack of consistency of study outcome measures. Although there is considerable RCT evidence comparing the use of specific products against water alone, or another product, for bathing, cleansing and nappy care, the power of this evidence is reduced due to inconsistency of outcome measures in terms of outcome, treatment site or time-point. The development of a core outcome measure set is advocated for trials assessing skin care practices.

### Implications for Practice

This review offers health professionals best evidence available on which to base their advice. Of those studies with comparative outcomes, the evidence indicates no difference between the specific products tested and water alone; offering parents a choice in their baby skin care regimen.

### Protocol available:

### Keywords

Skin care, term baby, systematic review

### Introduction

Baby skin care is arguably an area of maternity service provision considered to be of relatively lower priority compared to antenatal and intrapartum care. However, with the rising prevalence of childhood atopic eczema in the United Kingdom and uncertainties amongst midwives and parents about effective and safe baby skin care practices, current baby skin care advice given to parents by health professionals may be a contributory factor.

There are structural differences between baby and adult skin. The epidermis in babies is 20% thinner and the stratum corneum is 30% thinner (Stamatas et al. 2010), increasing susceptibility to permeability and dryness. The ratio of baby body surface to body weight is higher than that for

adults (Nikolovski et al. 2008), which means that topical agents may have a more intense effect on baby skin. Baby skin also has a propensity to greater trans-epidermal water loss [TEWL] and reduced stratum corneum hydration, reflecting a less effective skin barrier function (Chiou and Blume-Peytavi 2004; Nakagawa et al. 2004). Babies have a higher skin surface pH (low acidity) which amplifies protease activity and the breakdown of corneodesmosomes, the supportive connective components of the stratum corneum (Cork et al. 2009; Hachem et al. 2003). At birth, baby skin barrier is adequately developed to tolerate extrauterine environment; however, it continues to develop throughout the initial years of life (Fluhr et al. 2011; Stamatopoulou et al. 2011; Nikolovski et al. 2008).

Babies are susceptible to reduced epidermal barrier function. Clinical care and advice should be based on evidence-based recommendations about suitable topical agents which do not adversely alter or affect the skin barrier. This cautionary attitude is necessary in view of the increasing prevalence of childhood atopic eczema (Gupta et al. 2004; Taylor et al. 1984), affecting over 20% of children (Flohr and Mann 2014). This is not caused solely by genetic predisposition, but may be associated with environmental factors including the use of topically applied natural and/or commercial skin care products (Danby et al. 2013; 2011; Danby and Cork 2011).

Maternity and child health professionals input into parental practices during a child's early years. Most atopic eczema is diagnosed during the first year (Bieber 2008), most commonly around six months of age (Wadonda-Kabondo et al. 2003).

Parents have a choice of a wide range of products for baby skin, but there is insufficient evidence-based guidance to employ (Furber et al. 2012; Lavender et al. 2009). As traditional and anecdotal advice may be doing more harm than good, this systematic review was conducted with the aim of identifying the best available evidence to offer parents and health professionals information about optimum safe and effective skin care practices for term, healthy, newborn babies.

## Methods

The systematic review focused on common aspects of skin care including bathing, cleansing, nappy care, care of the hair/scalp, managing dry skin and baby massage. The age range for the review (birth to six months) was informed by the need to provide evidence to protect the integrity of newborn baby skin and prevent atopic eczema.

### *Search process*

A detailed search strategy was developed (Table 1) and tested using PICO (Richardson et al. 1995). To enhance the retrieval of qualitative papers a further search strategy was developed (Table 2) using SPIDER (Cooke et al. 2012). Appropriate Boolean operators were used to combine keywords. Table 3 provides an example of the full PICO search using Ovid Medline. References were managed in Endnote. A PRISMA flow diagram (Figure 1) represents the search process (Moher et al. 2009). The systematic three-step search, conducted in November 2015, employed the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- Medical Literature Analysis and Retrieval System Online: MEDLINE (1946 – November 2015)
- Excerpta Medica Database: EMBASE (1980 – November 2015)

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- The Cumulative Index to Nursing and Allied Health Literature: CINAHL (1937 – November 2015)
- ProQuest Dissertation and Theses (1861 – November 2015)
- OpenGrey (1980 – November 2015)
- British Nursing Index (1994 – November 2015)
- Maternity and Infant Care (1971 – November 2015)
- PsycINFO (1806 – November 2015)
- Allied and Complementary Medicine Database: AMED (1985 – November 2015)
- Clinical Trials Registry ([www.clinicaltrials.gov](http://www.clinicaltrials.gov))

In addition to the electronic database search the strategy included a citation search of retrieved papers and website exploration for major pharmaceutical and cosmetic companies; and an electronic search of the most topic relevant journals. English-language studies presented in abstract form were included if sufficient data were available or from contact with the study author.

[Please insert Tables 1-3 and Figure 1 about here]

### *Eligibility criteria*

All randomised [RCT] and quasi-randomised controlled trials (including trials in which the baby served as his/her own control), non-controlled trials and non-randomised experimental studies comparing the effects of any skin care regimens with an alternative or with no treatment were included. Qualitative papers were also included. Included papers were published in English between 2000 and 2015. This period was specified by the funder but earlier papers were included if regimens reflected current practice after review team agreement for completeness.

Newborn healthy term ( $\geq 37^{+0}$  weeks gestation) babies receiving common aspects of skin care from birth until six months of age were included. We excluded preterm ( $< 37^{+0}$  weeks gestation) babies, poorly term babies on neonatal units, or term babies with nappy rash, atopic eczema/dermatitis or receiving related treatment.

Primary outcomes included the change in stratum corneum hydration [termed ‘hydration’ hereafter], TEWL and skin surface pH within six months post-birth. Secondary outcomes included the change in skin assessment scores, erythema/rash, maternal satisfaction, systemic or cutaneous infection, atopic eczema, Neonatal Behavioural Assessment Scale (NBAS: Brazelton et al. 1987), economic analysis of skin care regimen and other skin-related outcomes not identified a priori by the research team but reported by study authors.

### *Data collection and analysis*

The process of quality appraisal, data extraction and analysis was guided by NICE (2014a). Two reviewers independently assessed all titles/abstracts of studies identified for inclusion. A form was designed for data extraction. For eligible studies, at least two reviewers extracted data. There were no discrepancies that required resolving by a third reviewer during eligibility screening or data extraction. Where the eligible studies were those authored by one of the team, an alternative member of the review team extracted and quality appraised data.

We contacted authors where study information was unclear, particularly where means and standard deviations were missing for continuous outcomes. Where possible, missing means and standard deviations were estimated from the sample size and 5-number summary (Inoue et al. 2013;Bland 2015) or, if quartiles were not available, from the sample size, median, maximum and minimum (Iarkowski et al. 2013;Hozo et al. 2005). Due to the expected skewness of outcome variables, missing means and standard deviations were not estimated when only medians and quartiles were available (Higgins and Green 2009).

Studies were quality assessed independently by two reviewers using the assessment tools (Effective Public Health Practice Project 2013;Spencer et al. 2003) recommended by NICE (2014a). For quantitative studies, quality assessment was presented by outcome using the GRADE approach (Kataoka et al. 2010;Guyatt et al. 2008):

- Strong – further research is very unlikely to change our confidence in the estimate of effect
- Moderate – further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
- Weak – further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

For qualitative studies, quality assessment was presented by individual study using the grading strategy developed by Downe et al. (2009) based on Lincoln & Guba (1985).

Meta-analysis was performed for quantitative data using Review Manager 5.3 when data from more than one study were available for an outcome. Forest plots highlight the individual study results together with the pooled estimate. Mean differences and odds ratios were used as the effect sizes for continuous and dichotomous outcomes respectively, except for comparisons of studies using tools to measure TEWL where the tools were known to produce readings that were not directly comparable. For such meta-analyses, standardised mean differences were used as effect sizes. Fixed-effect models were used unless the  $\chi^2$  test for heterogeneity showed  $P \leq 0.10$ , in which case random-effect models were fitted (Higgins and Green 2009). Because of a lack of consistency in outcomes, the maximum number of studies in a meta-analysis was only three. Meta-analysis results are reported to facilitate any future systematic review but should be interpreted with caution. Where meta-analysis was not possible, the summary of evidence includes descriptive statistics (mean values and standard deviations), effect sizes with confidence intervals [CI], and p-values. A narrative summary is presented to highlight evidence gaps, key factors affecting the results, their interpretation and summary of the key findings. No meta-analyses of subgroups of studies were performed because no more than three studies were found for any outcome. For the qualitative evidence, meta-synthesis was not possible due to insufficient evidence, quality or reporting. Data were aggregated in narrative form.

## Findings

### *Overview of studies*

We screened 3,062 papers; 2,929 did not meet the eligibility criteria (Figure 1). We included 26 eligible studies in 26 primary publications (Table 4). Studies included 16 RCTs, 3 non-randomised

experimental studies (including one pilot study), 1 mixed methods study (questionnaire/interview), and 6 qualitative studies. Most reports were of two-arm trials, but two were three-arm trials (Cooke et al. 2016;Dizon et al. 2010) and one was a four-arm trial (Garcia-Bartels et al. 2010). There were no economic or observational research papers which fulfilled the eligibility criteria. There were no eligible ongoing studies within the Clinical Trials Registry ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)).

[Please insert Table 4 about here]

We screened the full-text of 107 papers which did not meet the inclusion criteria. Of these, nine potentially eligible studies were excluded due to missing/unpublished data which was requested from the authors but not received at time of analysis (Coret et al. 2014;Gunt et al. 2014;Hengge 2014;Tierney and Schmalenberg 2014;larkowski et al. 2013;Inoue et al. 2013;Kataoka et al. 2010;Baig-Lewis et al. 2009;Takahashi et al. 2009). At the time of analysis, TEWL and hydration data were unavailable from Simpson et al. (2010) and hydration, skin surface pH, skin assessment score and skin colonization data were unavailable from Garcia Bartels et al. (2012). There were no identified studies investigating NBAS or economic analysis of skin care regimens. No papers were excluded due to poor quality.

#### *Demographic characteristics*

Included studies were mainly conducted post-2000. One pre-2000 study identified during citation checking (Rush 1986) was agreed for inclusion as it remained relevant. There were seven pre-2000 studies identified but excluded due to outdated clinical practices. Studies were conducted in high (UK, USA, Canada, Germany, Italy, Japan, Norway, Australia), middle (South Africa, Brazil, Pakistan, Zambia, Nigeria, Philippines) and low income settings (Tanzania, Ethiopia, Nepal).

In total, 10,167 babies participated in the quantitative studies. Most were born after 37<sup>+0</sup> weeks gestation, excepting 4% preterm per treatment group in Cutland et al. (2009) and one preterm baby per group in Kvenshagen et al. (2014). Data from these groups were included as they were homogeneous and did not skew the data. All babies weighed in excess of 3000g.

Interventions generally commenced within the first week post-birth, continuing for 4-8 weeks. Four studies continued the intervention for 6-24 months (Kvenshagen et al. 2014;Horimukai et al. 2014;Simpson et al. 2014; 2010). Application frequency ranged from once only to daily application for bathing and cleansing, and from twice daily to once weekly for dry skin management. Nappy care studies included frequency of every nappy change. Body treatment sites included forehead, abdomen, thigh, buttock, calf, forearm, popliteal fossa, umbilicus and fontanelle. There were no set doses to treatments except Lavender et al. (2013): 3 'squirts' per bath; Cooke et al. (2016): 4 drops of oil; Kvenshagen et al. (2014): 0.05 litres bath oil to 8 litres water; and Lowe et al. (2012): 6 grams of emollient.

#### *Risk of bias in included quantitative studies*

Table 5 illustrates the risk of bias for quantitative studies (n=20). Methods for adequate allocation concealment were reported in 12 trials. Of the remaining eight studies, three were not randomised and five did not report randomisation methods. In skin care studies it is not always possible to blind the participants as there may be no control product or emollient that has no effect on the skin. The participants were blinded to the intervention in only three studies (Cutland et al. 2009;Muggli

2009;Da Cunha et al. 2008). In one study, participants knew that they were in an intervention group but were blind to which intervention (Cooke et al. 2016). Assessors were blinded in 11 out of 19 studies. For one study (Muggli 2009) this is unclear. Fourteen studies achieved complete/near complete (>80%) evaluation of outcomes. Four studies achieved 71–79% evaluation of outcomes and this information was not reported in two studies. All of the declared outcomes appear to have been reported in all studies. Data collection methods were also assessed for validity and reliability (inter-rater reliability and instrument calibration). Methods appeared to be valid and reliable in only two studies and were not reported in four studies. In 14 studies the reported methods appear to be valid but we were unable to confirm that reliability was assessed.

[Please insert Table 5 about here]

#### *Specific skin care comparisons*

There were no data for review outcomes for hair/scalp care or for baby massage. Findings are presented for bathing and cleansing (8 comparisons), nappy care (2 comparisons) and management of dry skin (5 comparisons).

#### *Bathing and Cleansing*

Comparison 1: Newborn skin bathing and cleansing with *Johnson's® baby top-to-toe® bath* to water alone (Lavender et al. 2013; 2011;Dizon et al. 2010;Garcia-Bartels et al. 2010)

Strong evidence from two RCTs and moderate evidence from two RCTs in this comparison showed no evidence of any difference between *Johnson's® baby top-to-toe® bath* and water alone for any outcome measurements (TEWL; hydration; skin surface pH; skin assessment scores; erythema; maternal satisfaction; skin colonization) at any assessment time-points (2, 4 and 8 weeks) or at any treatment site (abdomen; thigh; forearm).

Only two of the 17 outcome measurements for TEWL, hydration and skin surface pH (at abdomen at 4 weeks and thigh at 4 weeks) had comparable data that were derived from at least three studies.

TEWL at 4 weeks post-birth indicated evidence of moderate heterogeneity at the abdomen ( $I^2=35\%$ ) and considerable heterogeneity at the thigh ( $I^2=63\%$ ). A random-effect model was fitted for the latter. The pooled effects at the abdomen (standardised mean difference -0.05, 95% CI -0.26 to 0.15, 3 studies, 361 babies) and thigh (standardised mean difference -0.10, 95% CI -0.50 to 0.30, 3 studies, 362 babies) were not significantly different from zero (figures 2 and 3).

[Please insert Figures 2 and 3 about here]

Hydration at 4 weeks post-birth indicated no evidence of heterogeneity at the abdomen or thigh ( $I^2=0\%$  and 15% respectively). The pooled effects at the abdomen (mean difference -0.89 arbitrary units [AU], 95% CI -2.39 to 0.62, 3 studies, 339 babies) and thigh (-0.38 AU, 95% CI -1.84 to 1.09, 3 studies, 339 babies) were not significantly different from zero (figures 4 and 5).

[Please insert Figures 4 and 5 about here]

Skin surface pH at 4 weeks post-birth indicated evidence of considerable heterogeneity at the abdomen and thigh ( $I^2=97\%$  for both). A random-effects model was fitted. The effect for the

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smallest study significantly favoured the wash product at the abdomen and thigh but this was in a different direction to the non-significant effects for larger studies. The pooled effects at the abdomen (mean difference -0.11, 95% CI -0.55 to 0.34, 3 studies, 360 babies) and thigh (-0.09, 95% CI -0.50 to 0.31, 3 studies, 360 babies) were not significantly different from zero (figures 6 and 7).

[Please insert Figures 6 and 7 about here]

Comparison 2: *Johnson's® baby top-to-toe® bath* and *Penaten® Baby Caring Facial and Body Cream* vs. water (Garcia-Bartels et al. 2010)

Moderate evidence from one RCT for this comparison was complicated by the intervention arm testing two products together (*Johnson's® baby top-to-toe® bath* and *Penaten® Baby Caring Facial and Body Cream*) against water alone. There was no clear pattern in the evidence for some of the measurements (TEWL; hydration; skin surface pH) at any assessment time-points (2, 4 and 8 weeks) or at any treatment site (abdomen; thigh; forehead). Other outcomes (skin assessment scores; skin colonization) showed no significant difference for any treatment site or time-point.

Comparison 3: Liquid baby cleanser and almond oil vs. water (Roberta et al. 2014)

Weak evidence from one RCT for this comparison indicated higher TEWL in the group using an undefined liquid baby cleanser and almond oil compared to the group using water alone at 10 days at both the forearm and the popliteal fossa. Results are complicated by there being two treatments in the intervention arm and so individual effects cannot be determined.

Comparison 4: *Baby Sebamed® Baby Liquid Cleanser* vs. water (Dizon et al. 2010)

Moderate evidence from one RCT for this comparison indicates no evidence of any difference between *Baby Sebamed® Baby Liquid Cleanser* and water alone for any measurements (TEWL; hydration; skin surface pH; skin assessment scores; maternal satisfaction) at 7 days at the calf.

Comparison 5: *Johnson's® baby top-to-toe® bath* vs. *Baby Sebamed® Baby Liquid Cleanser* (Dizon et al. 2010)

Moderate evidence from one RCT for this comparison indicates no evidence of any difference between *Johnson's® baby top-to-toe® bath* and *Baby Sebamed® Baby Liquid Cleanser* for any measurements (TEWL; hydration; skin surface pH; skin assessment scores; maternal satisfaction) at 7 days at the calf.

Comparison 6: Chlorhexidine wipes vs. water (Cutland et al. 2009)

Strong evidence from one RCT for this comparison indicates no evidence of any difference between chlorhexidine wipes and water alone for infection at 3 days.

Comparison 7: Chlorhexidine 0.4% liquid soap vs. pH neutral liquid soap (Da Cunha et al. 2008)

Moderate evidence from one RCT for this comparison indicates no evidence of any difference between chlorhexidine 0.4% liquid soap and pH neutral liquid soap for infection at 30 minutes or 24 hours after bathing; for skin colonization the effect favoured chlorhexidine 0.4% liquid soap.

Comparison 8: pH neutral soap vs. water (Medves and O'Brien 2001; Rush 1986)

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Weak evidence from two RCTs for this comparison indicates no evidence of any difference between pH neutral soap and water alone for skin colonization at the umbilicus or the fontanelle at 60 minutes or 24 hours after bathing or at the umbilicus at 4 days after bathing.

### Nappy care

Comparison 1: Alcohol free baby wipe vs. water (Furber et al. 2012; Garcia-Bartels et al. 2012; Lavender et al. 2012)

There was strong evidence from one RCT and one mixed-method study (structured interviews and diaries), and moderate evidence from one RCT for this comparison, but complete data from the RCTs were only available for TEWL. TEWL was consistently but not significantly lower in the group using baby wipes at 4 weeks on the buttock. Maternal satisfaction was also higher in the baby wipe group. There was no evidence of any difference between baby wipes and water alone for hydration, erythema or skin colonization. For skin surface pH the effect favoured cotton wool and water.

Comparison 2: *Penaten® cream* vs. *Efamol® evening primrose oil* (Muggli 2009)

Weak evidence from one RCT for this comparison indicates no evidence of any difference between newborn nappy care with *Penaten® cream* and *Efamol® evening primrose oil* at the buttock during an eight week treatment period for babies between the age of 2 weeks and 6 months.

### Management of dry skin

Comparison 1: Olive oil vs. no oil (Cooke et al. 2016)

Strong evidence from one RCT for this comparison indicates that olive oil impedes the development of the lipid structure of the skin barrier; however the skin was more hydrated in the olive oil group (dual effect explained by triglyceride lipolysis). There was no difference in TEWL, skin surface pH, erythema or skin assessment score between the groups.

Comparison 2: Sunflower oil vs. no oil (Cooke et al. 2016)

Strong evidence from one RCT for this comparison indicates that sunflower oil impedes the development of the lipid structure of the skin barrier; however, the skin was more hydrated in the sunflower oil group (dual effect explained by triglyceride lipolysis). There was no difference in TEWL, skin surface pH, erythema or skin assessment score between the groups.

Comparison 3: Olive oil vs. sunflower oil (Cooke et al. 2016)

Strong evidence from one RCT for this comparison indicates no difference in change in lipid structure, TEWL, hydration, skin surface pH, erythema or skin assessment scores between the olive oil and sunflower oil groups.

Comparison 4: Emollient vs. no treatment (Horimukai et al. 2014; Simpson et al. 2014; 2010; Lowe et al. 2012; Garcia-Bartels et al. 2011; 2010)

Strong evidence from one RCT, moderate evidence from one RCT and weak evidence from two RCTs and two experimental studies for this comparison indicates that overall, for hydration the effect favoured using emollient, particularly at 4 weeks and 8 weeks. There was no clear pattern in the

evidence for TEWL or skin surface pH. Other outcomes (skin assessment scores; infection) had no significant difference between treatment groups. Incidence of atopic eczema was reduced at 26 weeks in babies using emollient in two studies. However, babies using emollient were less likely to develop eczema at 32 weeks in one study but with no significant difference between the groups (although this is just outside the upper age range for babies in the review).

Comparison 5: Daily oil bath vs. normal care (Kvenshagen et al. 2014)

Weak evidence from one experimental study for this comparison indicates no difference in absence of xerosis or incidence of atopic eczema between the daily oil bath and normal care groups.

#### *Qualitative synthesis*

Table 6 illustrates the included qualitative study characteristics: seven studies included for review were conducted in the UK, Pakistan, Nepal, Nigeria, Ethiopia, Zambia and Tanzania. Three studies were qualitative only (Adejuyigbe et al. 2015; Sacks et al. 2015; Lavender et al. 2009); four were mixed-methods of which for three (Shamba et al. 2014; Fikree et al. 2005; Mullany et al. 2005) only the qualitative component fulfilled the inclusion criteria, and for one (Furber et al. 2012) both components were included in the review.

[Please insert Table 6 about here]

Three studies were methodologically strong (Shamba et al. 2014; Furber et al. 2012; Lavender et al. 2009) with a clear sampling strategy, data collection and analysis strategy and reporting, and a clear and cohesive link between the data, the interpretation and the conclusions. Two studies were of poor methodological quality (Fikree et al. 2005; Mullany et al. 2005): sampling strategy was unclear, and there was no thematic analysis or interpretation. In one study (Fikree et al. 2005) there was a superficial link between the data and conclusion, but for the other (Mullany et al. 2005) no data were presented. There was a similar lack of evidence of thematic analysis and link between the data and conclusions in Sacks et al. (2015); however this study was graded as moderate quality due to acknowledging reflexivity, ethical consideration and clear sampling and data collection strategies. Adejuyigbe et al. (2015) was also graded as moderate quality. This study was well designed and conducted, but there was no acknowledgement of reflexivity and the sample size was unclear.

Due to the dearth of qualitative evidence with similar focus, metasynthesis was inappropriate. Only five studies were deemed to be sufficiently robust for synthesis (Adejuyigbe et al. 2015; Sacks et al. 2015; Shamba et al. 2014; Furber et al. 2012; Lavender et al. 2009); however, their aims were not congruent. The three African studies focused on thermal care, limiting transferability to UK settings. The two UK studies considered different aspects of baby skin care. These papers were therefore considered narratively.

African studies found that traditional, cultural and symbolic factors influence practices which may be harmful, such as prioritising the mother's well-being, early and frequent baby bathing, night bathing with cold water and applying harmful substances to the skin such as cooking oil, powders made of

roots, burnt gourds or ash. All of these studies highlighted the need for behaviour change to improve and promote knowledge about best practice.

In both UK studies (Furber et al. 2012; Lavender et al. 2009), living with the argument ‘water is best’ continued even though the studies were conducted three years apart; participants were endeavouring to conform to guidelines despite not always wanting to. Lavender’s study found that mothers and health professionals felt that they needed to ‘toe the party line’ with regard to using water alone for bathing and cleansing.

“Yeah when the midwives were in the hospital I did [use water and cotton wool] because I knew they’d shout at you”  
(Lavender et al. 2009; p116)

In the later study by Furber et al. (2012), the authors suggest that mothers were ‘living with the rhetoric’ that water was best but felt reassured that they could use the commercial product being tested in the study.

“Had friend round today (midwife) and she was surprised that I was using baby wipes and not cotton wool. I explained there were no concerns on my part and baby wasn’t affected by using the baby wipes”  
(Furber et al. 2012; pE23)

Lavender’s study found that the majority of health professionals were promoting topical oil for dry skin or massage, believing that traditional natural products were safer than pharmaceutical/cosmetic formulations.

#### Discussion

##### *What does this review add to existing knowledge?*

This review can assist health professionals in consolidating their knowledge of baby skin care. This robust critical appraisal and synthesis offers the best available evidence and can be used by health professionals to support informed choice for women and families about baby skin care.

Until recently, there has been little robust research or its appraisal or synthesis to guide practice in safe and effective baby skin care. Consequently, health professionals have used tradition and personal experience to guide women (Lavender et al. 2009). Now stronger evidence is emerging which demonstrates that specific baby wash and wipes products are equivalent to water alone in relation to key outcomes of TEWL, hydration, skin surface pH, skin assessment scores and erythema. Other evidence indicates that daily full-body emollient application may be beneficial to prevent development of atopic eczema in babies who have a genetic predisposition. However, using topically applied olive or sunflower oil may impede the development of skin barrier function in healthy term babies.

##### *What is the quality of the evidence base?*

There was a high level of poor study reporting, an issue noted by previous reviews (Blume-Peytavi et al. 2012; Crozier and Macdonald 2010). Eighteen study authors (from 133; 14%) were contacted for eligibility queries and/or to request additional data, but only six responded. Authors conducting

trials should adhere to the CONSORT RCT reporting guidance (Schultz et al. 2010), the TREND statement for reporting non-randomised trials (Des Jarlais et al. 2004) and the STROBE statement for observational studies (von Elm et al. 2007). The review team recognised in particular that it is insufficient to report data only in graphical form, as it is impossible to read data accurately in this format. Means, standard deviations, number per group, CIs and p-values should all be reported in the text as appropriate. When distributions are skewed and medians are used to summarise the centre, they should be accompanied by maxima, minima and quartiles so that means and standard deviations can be estimated for meta-analysis. Systematic reviews are labour intensive but rank at the top of the hierarchy of evidence (Guyatt et al. 1995). Study authors and journal editors should ensure that publications include the most complete and precise data possible.

The strength of the qualitative evidence ranged from very weak to very strong. Only five studies were deemed sufficiently robust for synthesis (Adejuyigbe et al. 2015; Sacks et al. 2015; Shamba et al. 2014; Furber et al. 2012; Lavender et al. 2009). Unfortunately study aims were not congruent and meta-synthesis impossible. Stronger studies had a clearer sampling strategy, data collection and analysis strategy and reporting, and a clear and cohesive link between the data, the interpretation and the conclusions. Study authors should be guided by the COREQ statement (Tong et al. 2007) for reporting qualitative studies to aid future meta-synthesis.

*Were there any potential biases in the review process?*

The primary concern in any review process is the possibility that findings are subject to publication or other reporting biases. We endeavoured to minimise any bias by screening the reference lists of included studies and searching for conference proceedings to identify studies not yet published. Meta-analyses did not contain sufficient trials to assess the funnel plots as a means of identifying publication or reporting bias.

The quality of study reporting was poor relating to both methods and data and some studies were graded as methodologically poor in the absence of further information.

*What are the gaps in the evidence base?*

There are a number of areas where evidence exists, but due to heterogeneity, the data could not be pooled for meta-analysis. Studies had different outcome measures, measured at different time-points and/or on different body sites. There is a need to develop an appropriate core outcome set for baby skin care research, registered with the COMET Initiative (2016), to inform the design of future quantitative evaluative studies. Williamson et al. (2012) suggest that a core outcome set can minimise difficulties caused by heterogeneity and can also minimise outcome reporting bias. Existing work, such as the Harmonising Outcome Measures for Eczema (HOME) statement (Schmitt et al. 2014) for assessment of clinical signs of atopic eczema in trials, could inform this core outcome set. Having a core outcome set does not preclude the use of other outcome measures, but ensures a minimum core data set for comparison.

There is very little qualitative evidence exploring health professionals' and parents' concerns and preferences and the social role of bathing, or quantitative evidence investigating the economic costs of skin care regimens, optimal frequency of bathing, water hardness pertaining to newborn skin,

nappy barrier creams as a prevention rather than a treatment, care of the hair and scalp and skin related outcomes for baby massage. More research is required in these areas.

Even with the review covering an age range of 0-6 months, there have been few studies with a follow-up time-point to assess any correlation between skin products used from birth and the development of atopic eczema. The most robust trial evidence (Cooke et al. 2016; Horimukai et al. 2014; Lavender et al. 2013; 2012; 2011; Garcia-Bartels et al. 2012; 2011; 2010; Dizon et al. 2010) has assessed TEWL, hydration, skin surface pH, lipid structure, skin assessment scores and erythema, all of which can be indicators of a defective skin barrier function. Unfortunately inconsistency of measured outcomes prevents pooling of data for meta-analysis.

Only two large trials (Horimukai et al. 2014; Simpson et al. 2014) considered incidence of atopic eczema at 6 months of age but both of these recruited from a high risk population. Only 45% of diagnoses are made in the first six months after birth and 60% in the first year of life (Bieber 2008). Future studies investigating the impact of product use on the skin of healthy babies should aim to include this outcome at 6 and 12 months, and for longer durations if possible.

#### *What are the implications for practice?*

The review highlights the need for education and training to be developed, related to understanding the current evidence base and the impact this evidence has on clinical practice. It increases awareness of the effect of certain products on baby skin and their potential link to the development of atopic eczema. Education and training should be targeted to different audiences including health professionals, parents, hospital Trusts and service providers such as the International Association of Infant Massage.

NICE Postnatal Care Guidelines (2014b) include only one relevant non-evidence-based standard (1.4.23) for baby skin care (Table 7), which has not been updated since 2006.

[Please insert Table 7 about here]

This review has shown that specific agents and wipes can be used as an alternative to water alone, highlighted in several robust clinical trials since 2006 (Cooke et al. 2016; Horimukai et al. 2014; Simpson et al. 2014; Lavender et al. 2013; 2012; 2011; Garcia-Bartels et al. 2012; 2011; 2010; Dizon et al. 2010). In addition, the NICE guidance also suggests that soap may be used, but soap may contain sodium lauryl sulphate (SLS) that disrupts skin barrier function (Danby and Cork 2011). The reviewers consider that there is compelling need to revise current clinical guidance.

#### Conclusions

There are uncertainties amongst midwives and health professionals about effective and safe baby skin care practices. It is possible that by providing traditional and anecdotal advice to parents, which may be detrimental to skin barrier function, health professionals are a contributory factor in the rising prevalence of UK childhood atopic eczema.

This review has reported the available evidence for the five main aspects of healthy baby skin care. Twenty studies (7 strong, 4 moderate, 9 weak) were included in the quantitative review, and seven

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studies (3 strong, 2 moderate, 2 weak) were included in the qualitative review. It is evident that current UK clinical guidelines do not embrace the most contemporary evidence.

There is a growing body of robust evidence for bathing and cleansing, nappy care and management of dry skin, and a dearth of evidence for hair/scalp care and baby massage. Recent clinical trials investigating wash and wipe products found that a number are equivalent to water alone in their effect on skin barrier function. This means that health professionals can promote some choice to parents rather than advocating water only.

Meta-analysis was impeded by a lack of consistency of study outcome measures in many of the studies which fulfilled the review eligibility criteria. More studies could be included in meta-analysis if research in baby skin care adopted a core outcome measure set. Development of baby skin care core outcome measures is recommended.

It is imperative that the review findings are now addressed to improve education and training, and there is a compelling need to provide clear updated guidelines reflecting the appraisal and synthesis of current evidence for midwives, parents and other maternity service providers.

### Ethical Statement

#### 1. Conflict of interest

The research team members have some papers in the topic area which are published, under review or in press. No team members reviewed their own papers. Professor Dame Tina Lavender, Dr Carol Bedwell and Dr Alison Cooke have acted as advisors to Johnson and Johnson. The trials led by Professor Dame Tina Lavender were funded by Johnson and Johnson, although these were investigator led and sponsored by the NHS Trusts.

#### 2. Ethical Approval

This work is a systematic review of the evidence and does not require ethical approval.

#### 3. Funding sources

This work was supported by a grant from the Royal College of Midwives.

#### 4. Clinical Trial Registry

Not applicable

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**Table 1: PICO search strategy (Richardson et al. 1995)**

Population	infant* OR bab* OR neonat* OR newborn*
Intervention	(skin* OR skin care OR scalp OR cord OR umbilic*) AND (oil* OR therap* OR treatment* OR bath* OR clean* OR nap* OR diaper* OR massag* OR soap* OR wash* OR detergent* OR shampoo* OR wipe* OR product*)
Comparison	(skin* OR skin care OR scalp OR cord OR umbilic*) AND (emollient* OR cream* OR moistur* OR lubricant* OR powder* OR lotion* OR ointment* OR cloth* OR towel* OR sponge* OR cotton wool OR gauze)
Outcome	skin barrier* OR TEWL OR trans epidermal water loss OR stratum corneum hydration OR skin surface hydration OR hydration OR water loss OR skin pH OR erythema OR rash* OR skin ADJ3 score* OR dry skin OR xerosis OR microbio* OR skin development OR vernix OR seborrh?eic

Quantitative Search using (P) AND (I OR C) AND (O)

**Table 2: SPIDER search strategy (Cooke et al. 2012)**

Sample	infant* OR bab* OR neonat* OR newborn* OR parent* OR mother* OR father* OR maternal OR paternal
Phenomenon of Interest	(skin* OR skin care OR scalp OR cord OR umbilic* OR dry skin) AND (oil* OR therap* OR treatment* OR bath* OR clean* OR nap* OR diaper* OR massag* OR soap* OR wash* OR detergent* OR shampoo* OR wipe* OR product* OR emollient* OR cream* OR moistur* OR lubricant* OR powder* OR lotion* OR ointment* OR cloth* OR towel* OR sponge* OR cotton wool OR gauze)
Design	questionnaire* OR survey* OR interview* OR focus group* OR case stud* OR observ* view* OR experience* OR opinion* OR attitude* OR perce* OR belie* OR feel* OR know* OR understand*
Evaluation	
Research type	qualitative OR mixed method*
	Qualitative Search using [S AND P of I] AND [D OR E OR R]

**Table 3: Search Strategy: Ovid Medline [limits: English; 2000 – current]**

1	Infant/
2	baby.mp
3	babies.mp
4	neonat*.mp
5	newborn*.mp
6	1 or 2 or 3 or 4 or 5
7	Skin/
8	Skin Care/
9	Scalp/
10	Umbilical Cord/
11	cutaneous.mp
12	Hair/
13	7 or 8 or 9 or 10 or 11 or 12
14	oil*.mp
15	therap*.mp
16	treatment*.mp
17	bath*.mp
18	clean*.mp
19	nap*.mp
20	diaper*.mp
21	Massage/
22	Soaps/
23	wash*.mp
24	Detergents/
25	shampoo*.mp
26	wipe*.mp
27	product*.mp
28	14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27
29	13 and 28
30	Emollients/
31	Skin Cream/
32	moisturi?er*.mp
33	lubricant*.mp
34	powder*.mp
35	lotion*.mp
36	Ointments/
37	cloth*.mp
38	towel*.mp
39	sponge*.mp
40	cotton wool.mp
41	gauze.mp
42	30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41
43	13 and 42
44	29 or 43
45	skin barrier*.mp
46	TEWL.mp

47	trans epidermal water loss.mp
48	transepidermal water loss.mp
49	stratum corneum hydration.mp
50	skin surface hydration.mp
51	hydration.mp
52	water loss.mp
53	skin pH.mp
54	Erythema/
55	rash*.mp
56	skin adj3 score*.mp
57	skin adj3 assess*.mp
58	skin adj3 tool*.mp
59	dry skin.mp
60	xerosis.mp
61	microbio*.mp
62	skin develop*.mp
63	Vernix Caseosa/
64	seborrh?eic.mp
65	45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64
66	6 and 44 and 65

**Table 4: Quantitative study characteristics**

QUANTITATIVE STUDIES (literature search November 2015)					
Author/date/country	Cooke et al. (2016) UK	Cutland et al. (2009) South Africa	Da Cunha et al. (2008) Brazil	Dizon et al. (2010) Philippines	Furber et al. (2012) UK
Focus	Management of dry skin	Bathing and cleansing	Bathing and cleansing	Bathing and cleansing	Nappy care
Aims and objectives	To assess the feasibility of a full trial to investigate the impact of using topical olive oil and sunflower oil on newborn skin	To assess the efficacy of chlorhexidine in early-onset neonatal sepsis	To compare S.aureus skin colonization rate 24 hrs post-first bath in normal term newborns bathed with chlorhexidine liquid soap and neutral soap	To evaluate the tolerability of two baby cleanser formulations on infantile skin compared to water alone	To explore complexity of nappy area cleansing reported by women participating in an RCT to compare a baby wipe with cotton wool/water
Design	Parallel group pilot RCT	Parallel group RCT	Parallel group RCT	Parallel group RCT	Mixed methods study
Participants	Healthy, term infants born between September 2013 and July 2014, ≥37 weeks of gestation and ≤72 hours old. Exclusion criteria: admission to neonatal unit, receiving phototherapy, participation in another clinical trial, medical complications, limb defects, non-traumatic impairment of epidermal integrity or skin disorder (n=115)	8129 newborn babies delivered between 1 April 2004 and 25 October 2007. Exclusion criteria: born by caesarean section, congenital malformation, face presentation, known allergy to chlorhexidine, maternal genital infection, maternal antepartum haemorrhage. The sample consisted of 4% preterm infants, but these were equally distributed across the two groups (n=8129)	Healthy, newborn term infants, 37-42 weeks gestation, Apgar score ≥7 in 1st and 5th minutes, delivered 13 Sept 2005 to 14 March 2006. Exclusion criteria: skin breakdown, congenital malformation, congenital infection, premature rupture of membranes over 18 hours, foetid amniotic fluid, HIV positive mother, mothers with suspicion of bacterial infection before delivery or presenting axillary	Healthy, term, Filipino infants. Exclusion criteria: prematurity, congenital problems (n=180)	Healthy, term infants born in the UK between February 2010 and October 2010, ≥37 weeks of gestation and ≤ 48 hours old. Exclusion criteria: admission to neonatal unit, phototherapy treatment, skin disorder, adoption, use of cloth diapers (n=280)

Intervention	Application of 4 drops of olive oil twice daily to left forearm, left thigh and abdomen (intervention 1) versus application of 4 drops of sunflower oil twice daily to left forearm, left thigh and abdomen (intervention 2) versus no treatment (control)	Full body wipe with chlorhexidine soaked cotton pads (excluding face/ears) as soon as possible after birth (intervention) versus chlorhexidine foot wipe. All babies bathed in water as per standard care before being wiped	temperature >37.8°C (n=93) 0.4% chlorhexidine liquid soap bath immediately (1-1.5 hours) after birth (intervention) versus neutral (pH=7) liquid soap bath immediately (1-1.5 hours) after birth (control)	J&J Baby Top-to-Toe whole body wash twice a week for two weeks (intervention 1) versus Sebamed baby whole body liquid cleanser twice a week for two weeks (intervention 2) versus lukewarm tap water whole body bathing twice a week for two weeks (control)	J&J Baby Fragrance Free wipes at each diaper change (intervention) versus cotton wool and water at each diaper change (control). Both groups could use Natusan nappy cream if required Maternal satisfaction
Outcomes	Change in structure of lipid lamellae; TEWL; hydration; skin surface pH; clinical observations. Measurement at left forearm, left thigh and abdomen at birth and 4 weeks	Neonatal sepsis within first 3 days of life, swabs taken from umbilicus, nares and outer ear	Skin colonization; sepsis. Swabs taken at right axilla immediately before first bath, 30 minutes after bath, and 24 hours after bath	Clinical assessment; skin hydration; skin surface pH; TEWL; skin oxyhemoglobin/deoxyhemoglobin; consumer satisfaction. Assessments conducted at baseline, 1 week and 2 weeks post-birth	
Overall conclusion	Both oil groups had significantly better hydration but significantly less improvement in lipid lamellae structure compared to the no oil group. Caution should be exercised when recommending oils for dry skin	Chlorhexidine neonatal wipes did not prevent neonatal sepsis	A first bath with chlorhexidine reduced <i>S.aureus</i> colonization on the newborn's skin in a 24 hour period	All three interventions used as whole body cleansers were efficacious and well tolerated by infants	Women are faced with a complex environment regarding diaper area cleansing and need clear evidence-based guidance on effective diaper area cleansing
Strength of evidence	STRONG	STRONG	MODERATE	MODERATE	STRONG

Author/date/country	Garcia Bartels et al. (2010) Germany	Garcia Bartels et al. (2011) Germany	Garcia Bartels et al. (2012) Germany	Horimukai et al. (2014) Japan	Kvenshagen et al. (2014) Norway
Focus	Bathing and cleansing	Management of dry skin	Nappy care	Management of dry skin	Management of dry skin
Aims and objectives	To compare the influence of three skin care regimens to bathing with water	To assess the effects of baby swimming and baby lotion on the skin barrier function of infants	To obtain baseline data on skin functional parameters about the influence of cleansing with baby wipes compared to cleansing with water	To investigate whether daily application of moisturizer to neonates at high risk for atopic eczema prevents the development of atopic eczema/allergic sensitization	To assess if xerosis , and possibly atopic eczema, could be reduced at 6 months of age by early introduction of frequent oil baths/facial fat cream in infants with dry skin
Design	Parallel group RCT	Parallel group RCT	Parallel group RCT	Parallel group RCT	Pilot experimental controlled study
Participants	Healthy, term	Healthy, term infants	Healthy, term	Healthy, term	Healthy

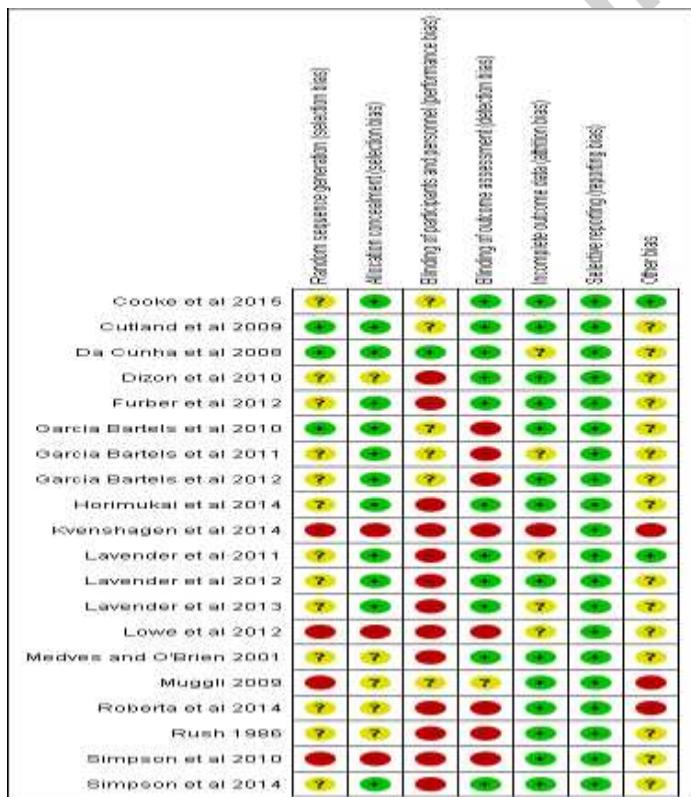
	neonates born Oct 2006 to May 2007, >37 weeks gestation, ≤48 hrs old. Exclusion criteria: sepsis, congenital malformation, asphyxia, hydronephrosis, intracranial haemorrhage, immunodeficient, pre-existing skin disease: eruptions >50% of body surface, skin maceration or inflammation /irritation, urticaria, acute/chronic diseases with temperatures < 35°C or > 40°C (n=64)	born between September 2009 and December 2009, ≥37 weeks of gestation, aged 3 to 6 months. Exclusion criteria: immunocompromised, severe illness, congenital skin disorder, skin irritation, pyrexia, participation in another trial (n=44)	infants born May 2007 to Oct 2007, ≥37 weeks gestation, ≤48 hrs old. Exclusion criteria: sepsis, congenital malformation, asphyxia, hydronephrosis, intracranial haemorrhage, immunodeficient, skin disease with eruptions > 50% of body surface, skin maceration or inflammation, urticaria, acute/chronic disease with temperature <35°C or >40°C (n=44)	infants with a family history of atopic dermatitis, born between November 2010 and November 2013. Exclusion criteria: treatment with corticosteroids, abnormal skin disorders (n=118)	infants with dry skin at 4 to 6 weeks of age between May 2011 and October 2011. Exclusion criteria: dry skin with signs of scratching or inflammation. The sample consisted of two preterm infants, one in each group (n=56)
Intervention	Wash gel (Penaten® Top to Toe Baby Gel) twice weekly day 7 to week 8 (intervention 1) vs. cream (Penaten® baby Caring Facial and Body Cream) twice weekly day 7 to week 8 (intervention 2) vs. wash gel plus cream twice weekly day 7 to week 8 (intervention 3) vs. water only twice weekly day 7 to week 8 (control)	Bübchen® Pflege Lotion applied to whole body once weekly after swimming (intervention) versus no lotion after swimming (control). Swimming session 24-40 minutes once weekly	Penaten® Baby wet wipes with aloe vera at each diaper change (intervention) versus moistened cotton wash cloth at each diaper change (control). Diaper change approximately 8 times per day for 4 weeks. Twice weekly bathing using no cleansers	Daily application of 2e Douhet emulsion to whole body surface from the first week of life for 32 weeks (intervention) versus no treatment (control). Petroleum jelly was also prescribed to both groups to use as required	Daily oil bath (0.5dl bath oil to 8 litres warm water) for ten minutes and application of Ceridal® fat emollient to the face (intervention) versus normal care (control)
Outcomes	1) TEWL; 2) hydration; 3) skin surface pH; 4) sebum; 5) NSCS; 6) microbiological colonization. 1)-5) measured at abdomen, thigh and buttock day 2, and weeks 2, 4 and 8. 6) measured at umbilicus day 2 and week 4	TEWL; hydration, skin surface pH; sebum; NSCS at forehead, abdomen, thigh and buttock, at baseline (within 4 weeks before first swim session), then weekly for 4 weeks before swimming session. Follow up 1 week after final swimming session	TEWL; hydration; skin surface pH; IL-1 $\alpha$ ; epidermal desquamation; microbiological colonization; NSCS. Measurements taken at buttock, abdomen and thigh day 2, day 14 and day 28	Incidence of atopic dermatitis; onset of allergic disease; allergic sensitization; TEWL; hydration; skin surface pH; skin colonization. Measurements taken at lower leg and forehead at baseline, week 4, week 12, week 24, week 32	Absence of dry skin at six months of age; presence of atopic dermatitis at six months of age. Measured using skin scoring system at baseline, 3 months and 6 months
Overall conclusion	Skin care regimens did not harm physiologic neonatal skin barrier adaptation within the first 8 weeks of life	Reaction of skin barrier function to baby swimming and skin care regimens showed variation between body areas	Neither of the two cleansing procedures harms skin barrier maturation within the first 4 weeks postpartum	Daily application of moisturizer during the first 32 weeks of life reduces the risk of atopic dermatitis in infants	Regular oil baths in infants seem to reduce xerosis and may possibly reduce atopic eczema
Strength of evidence	MODERATE	WEAK	MODERATE	STRONG	WEAK

Author/date/country	Lavender et al. (2011) UK	Lavender et al. (2012) UK	Lavender et al. (2013) UK	Lowe et al. (2012) Australia	Medves and O'Brien (2001) Canada
Focus	Bathing and cleansing	Nappy care	Bathing and cleansing	Management of dry skin	Bathing and cleansing
Aims and objectives	To produce baseline data which would inform decisions for a main trial design and to optimise the robustness of trial processes within the study setting	To examine the hypothesis that the use of a specifically formulated cleansing wipe on the nappy area of newborn infants (<1 month old) has an equivalent effect on skin hydration as cotton wool/water	To examine the hypothesis that the use of a wash product formulated for newborn (<1 month old) bathing is not inferior (no worse) to bathing with water only	To assess the safety and compliance with daily application of a ceramide-dominant triple lipid formula commencing in the neonatal period for the prevention of eczema	To compare colonization rates between infants bathed in soap and water and infants bathed in plain water
Design	Parallel group pilot RCT	Parallel group RCT	Parallel group RCT (non-inferiority)	Experimental non-controlled study	Parallel group RCT
Participants	Healthy, term infants born between November 2008 and November 2009, ≥37 weeks of gestation, <24 hours old. Exclusion criteria: admitted to neonatal unit, having phototherapy, limb defects, non-traumatic impairment of epidermal integrity or evidence of skin disorder, participation in another clinical trial (n=100)	Healthy, term infants born between February 2010 and October 2010, ≥37 weeks of gestation, ≤48 hours of age, using disposable diapers. Exclusion criteria: admission to neonatal unit, phototherapy treatment, limb defects, non-traumatic impairment of epidermal integrity, chromosomal abnormality, skin disorder, adoption (n=280)	Healthy, term infants born between February 2010 and March 2011, ≥37 weeks of gestation, <48 hours old. Exclusion criteria: admitted to neonatal unit, receiving phototherapy, limb defects, non-traumatic impairment of epidermal integrity, evidence of skin disorder, chromosomal abnormality, and adoption (n=308)	Healthy infants born March to June 2010, ≥36 weeks gestation (no infants were <37 weeks of gestation), <4 weeks old, with a family history of allergic disease (atopic dermatitis, asthma, allergic rhinitis or food allergy). Exclusion criteria: parent with known hypersensitivity to any of intervention cream ingredients, multiple birth, admission to neonatal unit (n=10)	Healthy, term infants born between 8 February 1999 and 9 June 1999, >37 weeks of gestation, Apgar score >7 at 5 minutes. Exclusion criteria: birth by caesarean section, admission to neonatal unit, physical abnormality, planned discharge before 24 hours old, HIV positive mother (n=140)
Intervention	Bathing with J&J Baby Top-to-Toe wash product at least 3 times a week (intervention) versus bathing with water and cotton wool at least 3 times a week (control)	J&J Baby Fragrance Free wipes at each diaper change (intervention) versus cotton wool and water at each diaper change (control). Both groups could use Natusan cream as required	Bathing with J&J Baby Top-to-Toe wash product (ratio 3 squirts per bath) at least 3 times per week (intervention) versus bathing with water alone at least 3 times per week (control)	Full body (excluding hands/face) daily application of Epiceram™ (approximately 6 grams) after bathing or at a regular time each day for 6 weeks	Bathing with a mild pH neutral soap (type not defined) and water (intervention) versus bathing in water alone (control)
Outcomes	TEWL; hydration, skin surface pH, clinical observations. Measurements taken at abdomen, thigh and forearm at baseline, 4 weeks and 8 weeks	Change in hydration from 48 hours to 4 weeks post-birth; change in TEWL; change in skin surface pH; erythema; microbial skin contaminants; diaper dermatitis. Measurements taken at buttock at baseline and 4 weeks post birth	TEWL at 14 days and 28 days; skin surface pH; hydration; Neonatal Skin Condition Score (NSCS); maternal satisfaction. Measurements on abdomen, thigh and forearm at baseline, 2 weeks and 4 weeks	Rate of compliance; adverse events; atopic dermatitis; TEWL; hydration; skin surface pH measured at the forearm and forehead at baseline and at 6 weeks	Colonization rates at the umbilicus before first bath, 1 hour after bath and 24 hours after birth

			weeks		
Overall conclusion	The pilot study produced valuable baseline data and important information on trial processes.	Baby wipes had an equivalent effect on skin hydration when compared with cotton wool/water	There were no differences between the newborn wash product and water	Results support the safety and parental compliance with daily applications of emollient for the prevention of eczema	Bathing with mild soap as opposed to bathing in water alone has minimal effect on skin bacterial colonization
Strength of evidence	STRONG	STRONG	STRONG	WEAK	WEAK
Author/date/country	Muggli (2009) Germany	Roberta et al. (2014) Italy	Rush (1986) Canada	Simpson et al. (2010) USA	Simpson et al. (2014) UK/USA
Focus	Nappy care	Management of dry skin	Bathing and cleansing	Management of dry skin	Management of dry skin
Aims and objectives	To determine if Efamol® evening primrose oil is suitable for baby skin care	To assess the effects of two different skincare practices on healthy skin barrier function maturation	To assess whether routine bathing of newborns would significantly reduce colonization rates to levels below those of unbathed babies	To determine the feasibility of skin barrier protection as a novel atopic dermatitis prevention strategy	To test whether skin barrier enhancement from birth represents a feasible strategy for reducing incidence of atopic eczema in high-risk neonates
Design	Parallel group RCT	Parallel group RCT	Parallel group RCT	Pilot experimental non-controlled study	Parallel group pilot RCT
Participants	Healthy, term infants (period of recruitment not reported), ≥37 weeks of gestation, aged 2 weeks to 6 months. Exclusion criteria: any skin disease, diaper dermatitis in the 4 weeks prior to recruitment (n=66)	Healthy, term infants born Oct 2012 to Dec 2012, ≤10 days old, no family history of atopic eczema or other skin conditions. Exclusion criteria: phototherapy, immunodeficient, relevant skin inflammation/irritation >50% of body surface, dermatological diagnosis for skin infection, ongoing medication, sepsis, systemic diseases (n=94)	Healthy, term infants born between 19 March 1984 and 7 May 1984, ≥37 weeks of gestation, Apgar score ≥9 at 5 minutes. Exclusion criteria: admission to neonatal unit (n=95)	Healthy, term infants born between November 2006 and November 2008, with family history of atopic dermatitis, ≥37 weeks of gestation, <7 days old. Exclusion criteria: congenital abnormality, hydrops fetalis, infection, significant dermatitis at birth, immunodeficiency, skin disorder, medical complications (n=22)	Healthy, term infants born between May 2010 and May 2011, ≥37 weeks of gestation, family history of atopic dermatitis. Exclusion criteria: mother taken lactobacillus rhamnosus supplements during pregnancy, congenital abnormality, hydrops fetalis, immunodeficiency, skin disorder (n=124)
Intervention	Application of Efamol® evening primrose oil to the buttock following diaper change (intervention) versus application of Penaten® cream following diaper change (control) for 8 weeks	Bathing with liquid baby cleanser (undefined) and moisturizer applied (almond oil) once daily (intervention) versus bathing with water-moistened cotton washcloth once daily (control). Complicated by use of two interventions in one group - unable to determine if effect of one is skewed by the other	Daily bathing with soap (type not defined) and water (intervention) versus no bathing (sponge off when soiled) (control)	Full body (excluding diaper area and scalp) application of Cetaphil® cream once daily (or more often) within 3 minutes of bathing. Participants could not use soap but could use fragrance free cleansers, petroleum jelly, suncream and there were no limits on frequency	Full body (excluding scalp) emollient therapy at least once daily starting within the first 3 weeks after birth (intervention) versus no treatment (control). In the intervention group, parents could choose from sunflower seed oil, doublebase gel and liquid paraffin 50% in white soft paraffin

				of bathing	
Outcomes	Parent reported clinical observations at baseline, day 28 and day 58	TEWL at the forearm and popliteal fossa at <24 hours and at 10 days	Bacterial colonization at the nose and umbilicus at day 4 (swab) and day 21 (telephone self-reporting by mother)	Incidence of skin-related adverse events; incidence/mean age of onset of atopic dermatitis; compliance; TEWL; hydration. Measurements at forearm at 1 month (exam), 3 months (telephone), 6 and 12 months (exam), 18 months (telephone) and 24 months (exam)	Incidence of atopic dermatitis at 6 months. Measurement at 10 days (telephone), 6 weeks (telephone), 12 weeks (exam), 18 weeks (telephone) and 24 weeks (exam)
Overall conclusion	Evening primrose oil could qualify as a safe and natural baby skin care product as efficacious as ointments/creams for prevention of nappy rash	Skincare regimens could influence the process of functional adaptation of the skin	There was no difference in the colonization rates between the routine bath and no-bath groups	Skin barrier repair from birth represents a novel and feasible approach to atopic dermatitis prevention	The results demonstrate that emollient therapy from birth represents a feasible, safe, and effective approach for atopic dermatitis prevention
Strength of evidence	WEAK	WEAK	WEAK	WEAK	WEAK

**Table 5: Risk of bias summary for quantitative studies (n=20): review authors' judgements about each risk of bias item for each included study**



**Table 6: Qualitative study characteristics**

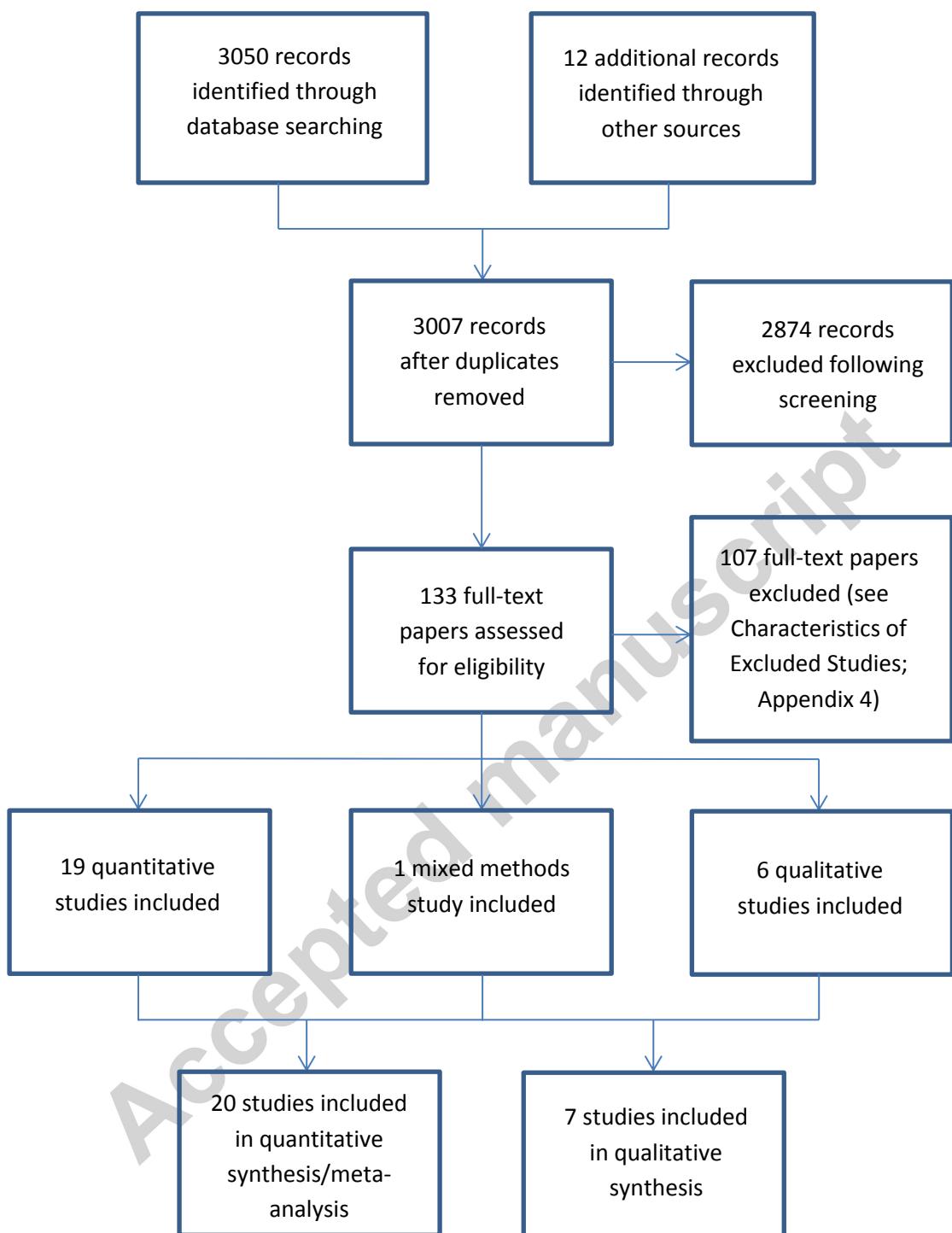
QUALITATIVE STUDIES (literature search November 2015)							
Author/date/country	Adejuyigbe et al. (2015) Africa	Fikree et al. (2005) Pakistan	Furber et al. (2012) UK	Lavender et al. (2009) UK	Mullany et al. (2005) Nepal	Sacks et al. (2015) Zambia	Shamba et al. (2014) Tanzania
Focus			Nappy care	Bathing and cleansing	Baby massage		
Theoretical perspective	Unclear	Unclear		Interpretive framework (Parahoo, 1997)	Unclear		
Design	Qualitative	Mixed methods	Mixed methods	Interview study	Mixed methods study (qualitative focus groups)	Qualitative	Mixed methods Grounded theory
Sampling strategy and sample size	Purposive and snowball sampling of mothers, grandmothers, health workers, fathers, birth attendants(n=unclear)	Sampling strategy unclear Muslim women (n=approx. 60)	Purposive sampling of participants in ongoing RCT (Lavender et al. 2012) (n=280)	Purposive sampling (n=56): midwives (n=20), health visitors (n=10), women in antenatal/postnatal period (n=26)	Purposive sampling of participants in ongoing trial of umbilical and skin cleansing with antiseptics (n=39)	Purposive sampling Women who had given birth at hospital or at home and birth attendants (n=75)	Purposive sampling New mothers and birth attendants (n=71)
Data collection methods	Interviews: narrative and in-depth; observation; field notes; audio recorded. Data managed NVivo	In-depth interviews Focus groups	Diaries; structured face-to-face interviews; telephone interviews. Transcribed verbatim Data managed manually	In depth interviews, broad topic areas, lasting 20-90 minutes Some longitudinal (n=22) Field notes taken	Focus groups, topic-led, and informal discussions with key informants such as shopkeepers, and family of study staff	Interviews; focus groups; observation Field notes Audio recorded Transcribed and translated using Atlas software	Narrative and in-depth interviews; focus groups Field notes Audio recorded Interviewer's translated verbatim
Analytic approach	Framework analysis Multiple analysts	No thematic analysis No interpretation	Thematic analysis Multiple analysts	Thematic analysis Multiple analysts	Unclear analysis. No themes presented. One verbatim quote	No thematic analysis Themes not generated from data	Constant comparative analysis Multiple analysts
Findings/conclusions	Variation between the four sites; Importance of warmth; Traditional beliefs; Sub-optimal care practices Conclusion: Need to promote knowledge about best practice	Daily massage common; reasons for massage: muscle relaxation and strengthening of bones Conclusion: Predominance of risky care practices. Promotion	Challenges and realities: practical realities; everyday life; living with the rhetoric that water is best Conclusion: clear evidence-based advice	Informed uncertainty: mirage of evidence; toeing the party line; influential marketing Conclusion: conflicting evidence	Mustard oil very common: >99% use for infant massage; sunflower oil not thought to be useful; massage used to promote strength, health, warmth	Frequent bathing (cold bathing at night to promote strength); vernix removed; emollients applied to whole body Conclusion: Thermal care coexists	Mothers priority for care; may increase cold babies; timing of bathing multi-factorial; skin-to-skin is a new concept Conclusion: Most thermal

**ACCEPTED MANUSCRIPT**

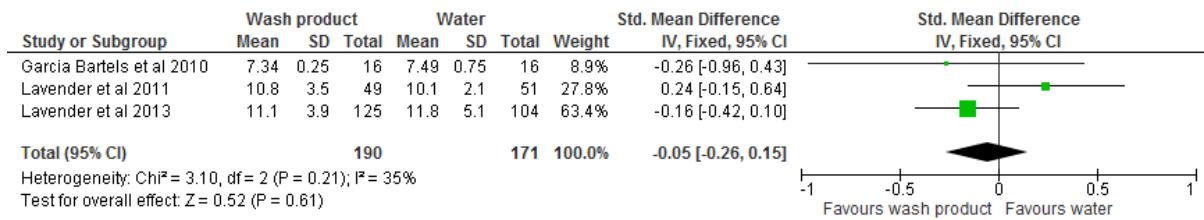
		of health education programme s needed	and guidance needed		Conclusion : Cultural, social and economic factors influence practices	with harmful practices. Behaviour change should be promoted	practices need improvement. Cultural and symbolic factors influence practices
Reporting	Clear, cohesive link between data, interpretation and conclusions	Superficial link between data and conclusion (no analysis evident)	Clear, cohesive link between data, interpretation and conclusions	Clear, cohesive link between data, interpretation and conclusions	No data illustrated No link between data and conclusion can be determined	Superficial link between data and conclusion (no analysis evident)	Clear, cohesive link between data, interpretation and conclusions
Reflexivity	Not reported	Not reported	Not reported	Influence on data acknowledged	Not reported	Influence on data acknowledged	Influence on data acknowledged
Strength/evidence	MODERATE	WEAK	STRONG	STRONG	WEAK	MODERATE	STRONG

**Table 7: NICE (2014b) Postnatal Care Guideline 1.4.23 (page 30)**

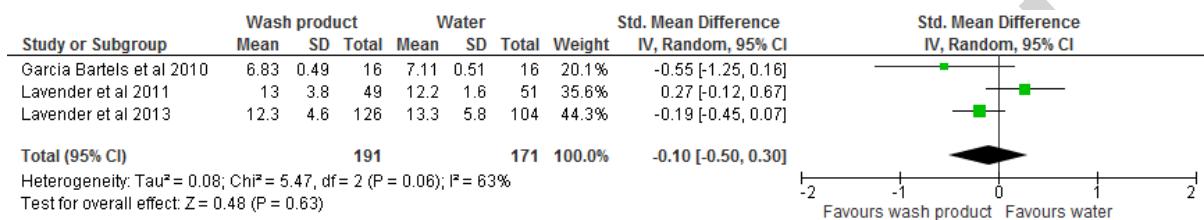
Parents should be advised that cleansing agents should not be added to a baby's bath water nor should lotions or medicated wipes be used. The only cleansing agent suggested, where it is needed, is a mild non-perfumed soap. [2006]
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**Figures:****Figure 1: PRISMA flow diagram (Moher et al. 2009)**

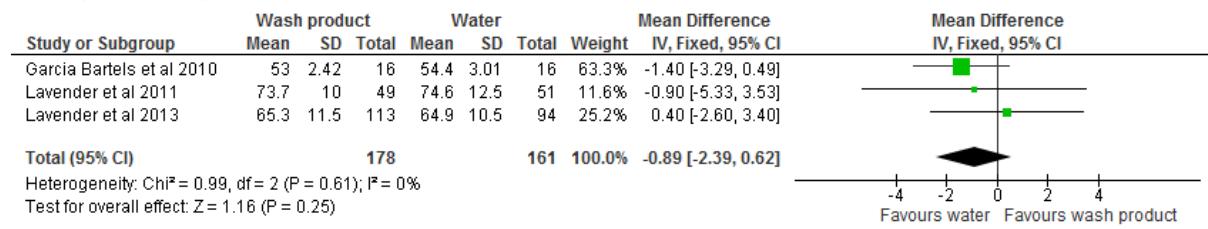
**Figure 2. Forest plot of comparison: 1 Newborn skin bathing and cleansing with Johnson's® baby top-to-toe® bath compared to water alone, outcome: TEWL at 4 weeks post-birth (abdomen)**



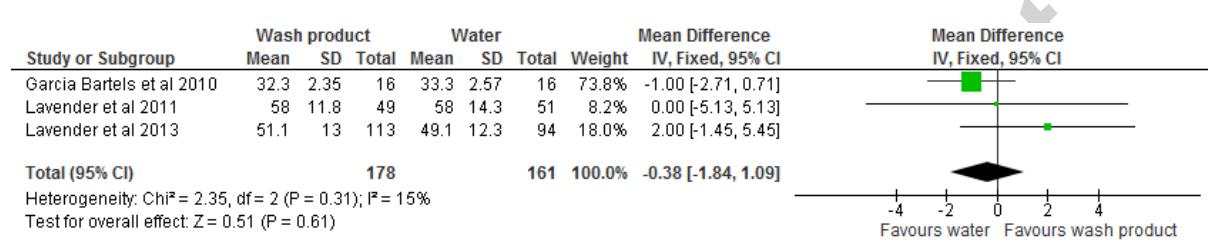
**Figure 3. Forest plot of comparison: 1 Newborn skin bathing and cleansing with Johnson's® baby top-to-toe® bath compared to water alone, outcome: TEWL at 4 weeks post-birth (thigh)**



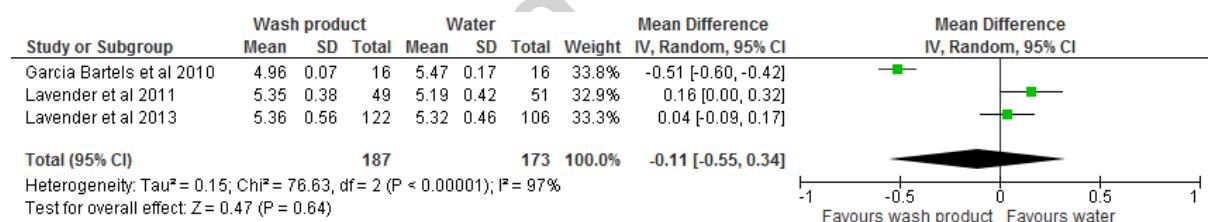
**Figure 4. Forest plot of comparison: 1 Newborn skin bathing and cleansing with Johnson's® baby top-to-toe® bath compared to water alone, outcome: Stratum corneum hydration at 4 weeks post-birth (abdomen)**



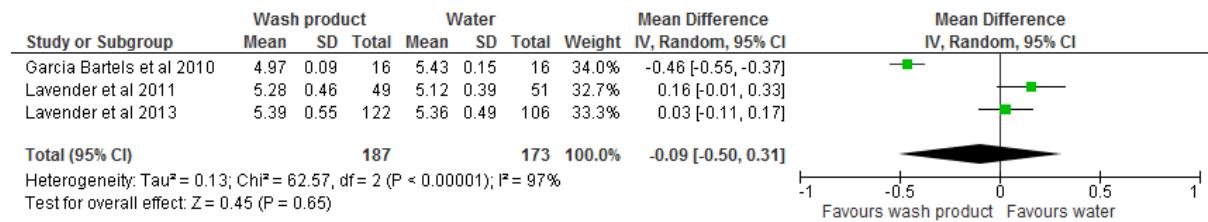
**Figure 5. Forest plot of comparison: 1 Newborn skin bathing and cleansing with Johnson's® baby top-to-toe® bath compared to water alone, outcome: Stratum corneum hydration at 4 weeks post-birth (thigh)**



**Figure 6. Forest plot of comparison: 1 Newborn skin bathing and cleansing with Johnson's® baby top-to-toe® bath compared to water alone, outcome: Skin surface pH at 4 weeks post-birth (abdomen)**



**Figure 7. Forest plot of comparison: 1 Newborn skin bathing and cleansing with Johnson's® baby top-to-toe® bath compared to water alone, outcome: Skin surface pH at 4 weeks post-birth (thigh)**



### Highlights

- Clear and current clinical guidelines for baby skin care are urgently needed
- Adherence to reporting guidelines is poor and a core outcome set is required
- Difficult to link skin care and eczema as few studies assess babies post-6 months
- There is often little difference between the effect of skin product and water alone
- Effect of baby massage on skin integrity requires further investigation