



Universidade de São Paulo
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Programa de Pós-Graduação em Saúde Mental

Effective Public Health Practice Project - EPHPP

Quality Assessment Tool for Quantitative Studies

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2020



Quality Assessment Tool for Quantitative Studies



- ✓ EPHPP - Fornecer evidências científicas para orientar e apoiar o Ministério de Saúde de Ontário (Canadá) na definição de requisitos mínimos para os serviços de saúde pública
- ✓ Divulgação de revisões sistemáticas da literatura sobre a efetividade de intervenções em saúde em nível internacional
- ✓ Desenvolvimento de um **instrumento de avaliação da qualidade metodológica** de estudos quantitativos sobre intervenções em saúde

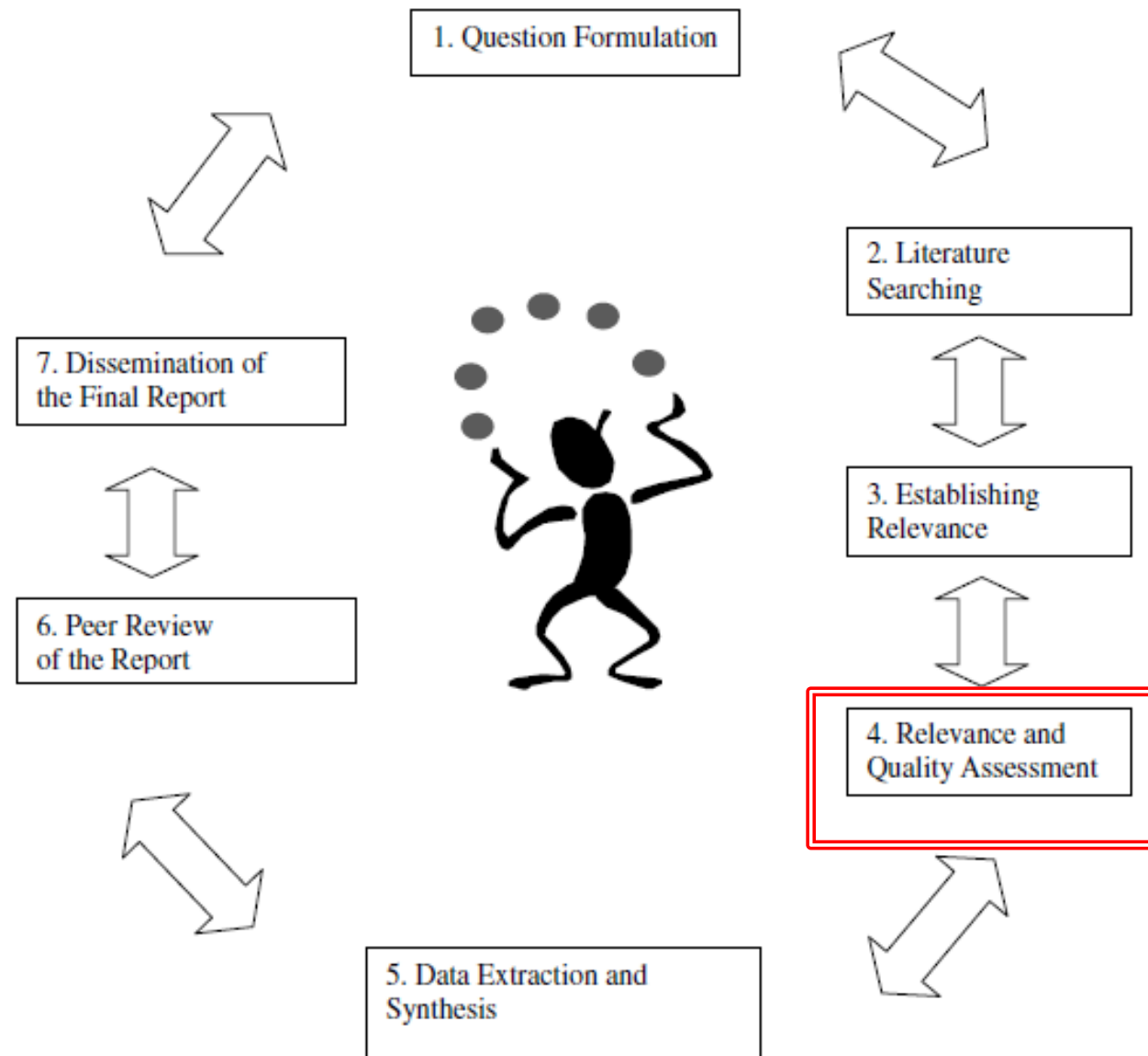


Figure 1. Steps in an EPHPP systematic review.

Thursday, October 22, 2020



Effective Public Healthcare Panacea Project

Quality Assessment Tool for Quantitative Studies

- [QA Tool PDF](#)
- [QA Dictionary PDF](#)
- [A Process for Systematically Reviewing the Literature: Providing the Research Evidence for Public Health Nursing Interventions](#)
Thomas, B.H., Ciliska, D., Dobbins, M., & Micucci, S. A process for systematically reviewing the literature: Providing the research evidence for public health nursing interventions. Worldviews on Evid Based Nurs. 2004; 1(3):176-184.
- [Assessment of Study Quality for systematic Reviews: A Comparison of the Cochrane Collaboration Risk of Bias Tool and the Effective Public Health Practice Project Quality Assessment tool: Methodological Research.](#)
Armijo-Olivo, S., Stiles, C.R., Hagen, N.A., Biondo, P.D., Cummings, G.G. Assessment of study quality for systematic reviews: a comparison of the Cochrane Collaboration Risk of Bias Tool and the Effective Public Health Practice Project Quality

MENU

- How Much Does Canada Spend on Health Care?
- Canada Health Act (CHA)
- [QA Tool](#)
- Health care issues in Canada

CANADA'S HEALTHCARE SYSTEM



Quality Assessment Tool for Quantitative Studies



- ✓ Muitos estudos sobre a efetividade de intervenções para promoção de saúde / saúde pública não são ensaios clínicos randomizados controlados (RCTs)
- ✓ Desenvolvimento de uma ferramenta de avaliação de qualidade metodológica apropriada para abranger uma variabilidade de estudos com diversos delineamentos de pesquisa
- ✓ Avaliação de **oito componentes** relacionados ao **método** dos estudos

Quality Assessment Tool for Quantitative Studies



Componentes de avaliação da qualidade metodológica

- ☐ Viés de seleção dos participantes
- ☐ Delineamento do estudo
- ☐ Controle de fatores de confusão
- ☐ Condição cega dos avaliadores e participantes
- ☐ Metodologia de coleta de dados
- ☐ Perda amostral
- ☐ Integridade da intervenção
- ☐ Análise de dados

Pontuação e Classificação de cada item

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	SELECTION BIAS	STRONG	MODERATE	WEAK
		1	2	3
B	STUDY DESIGN	STRONG	MODERATE	WEAK
		1	2	3
C	CONFOUNDERS	STRONG	MODERATE	WEAK
		1	2	3
D	BLINDING	STRONG	MODERATE	WEAK
		1	2	3
E	DATA COLLECTION METHOD	STRONG	MODERATE	WEAK
		1	2	3
F	WITHDRAWALS AND DROPOUTS	STRONG	MODERATE	WEAK
		1	2	3
				Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

- | | | |
|---|----------|----------------------------|
| 1 | STRONG | (no WEAK ratings) |
| 2 | MODERATE | (one WEAK rating) |
| 3 | WEAK | (two or more WEAK ratings) |

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☐ Viés de seleção dos participantes

❖ Os indivíduos selecionados para participar do estudo são representativos da população-alvo?

Participantes têm maior probabilidade de serem representativos da população-alvo se forem selecionados aleatoriamente de uma lista abrangente de indivíduos **(muito provável)**. Eles podem não ser representativos se forem encaminhados de uma fonte (por exemplo, clínica) de uma maneira sistemática **(pouco provável)** ou autorreferidos **(improvável)**

❖ Qual porcentagem de indivíduos selecionados concordou em participar?

Porcentagem de indivíduos nos grupos intervenção e controle que concordaram em participar do estudo: **(80 a 100%)** **(60 a 79%)** **(menos de 60%)**

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☐ Viés de seleção dos participantes

FORTE É muito provável que os indivíduos selecionados sejam representativos da população-alvo e há mais de 80% de participação

MODERADO Os indivíduos selecionados têm pelo menos pouca probabilidade de serem representativos da população-alvo e há 60 - 79% de participação

FRACO Os indivíduos selecionados provavelmente não são representativos da população-alvo; ou há menos de 60% de participação; ou a seleção não é descrita e o nível de participação não é descrito

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☐ Delineamento do estudo

❖ Indicar o delineamento do estudo

❖ O estudo foi descrito como randomizado?

Considere **SIM** se os autores usarem termos como alocação aleatória ou atribuição aleatória

❖ Em caso afirmativo, o método de randomização foi descrito?

Considere **SIM** se os autores descreverem algum método usado para gerar uma sequência de alocação aleatória

❖ Em caso afirmativo, o método de randomização foi apropriado?

Considere **SIM** se a sequência de randomização permitiu que cada participante do estudo tivesse a mesma chance de receber cada intervenção e os pesquisadores não puderam prever qual intervenção seria para o próximo participante

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☐ Delineamento do estudo

FORTE Ensaios clínicos randomizados controlados ou ensaios clínicos controlados

MODERADO Estudo analítico de coorte, estudo caso-controle, estudo de coorte ou uma série temporal interrompida

FRACO Estudos com outros tipos de delineamentos ou aqueles que não indicaram o delineamento realizado

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☐ Controle de fatores de confusão

❖ Houve diferenças importantes entre os grupos antes da intervenção?

Os grupos podem não estar equilibrados com relação a variáveis importantes antes da intervenção. Os autores devem indicar se os fatores de confusão foram controlados, ou na análise. Se a alocação para os grupos de intervenção e controle for randomizada, os autores devem relatar que os grupos foram equilibrados no início do estudo com relação aos fatores de confusão (no texto ou em uma tabela)

❖ Em caso afirmativo, indique a porcentagem de fatores de confusão relevantes que foram controlados.

(80 a 100%) (60 a 79%) (menos de 60%)

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☐ Controle de fatores de confusão

FORTE Estudos que controlaram pelo menos 80% dos fatores de confusão relevantes

MODERADO Estudos que controlaram 60-79% dos fatores de confusão relevantes

FRACO Estudos que controlaram menos de 60% dos fatores de confusão relevantes **ou** o controle de fatores de confusão não foi descrito

Quality Assessment Tool for Quantitative Studies



☐ **Condição cega dos avaliadores e participantes**

❖ Os avaliadores estavam cientes da intervenção ou status de exposição dos participantes?

Os avaliadores devem ser descritos como cegos para quais participantes estavam nos grupos controle e intervenção

❖ Os participantes do estudo estavam cientes da questão da pesquisa?

Os participantes do estudo não devem estar cientes (ou seja, cegos) para a questão da pesquisa

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☐ **Condição cega dos avaliadores e participantes**

FORTE O avaliador não está ciente do status de intervenção dos participantes **e** os participantes do estudo não estão cientes da questão de pesquisa

MODERADO O avaliador não está ciente do status de intervenção dos participantes **ou** os participantes do estudo não estão cientes da questão da pesquisa

FRACO O avaliador está ciente do status de intervenção dos participantes **e** os participantes do estudo estão cientes da questão de pesquisa

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☐ Metodologia de coleta de dados

- ❖ Os instrumentos de coleta de dados possuem validade?
- ❖ Os instrumentos de coleta de dados possuem confiabilidade?

Os instrumentos para avaliação dos desfechos primários devem apresentar validade e confiabilidade.

A validade e confiabilidade podem ser relatadas no estudo ou em outro estudo referenciado.

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☐ Metodologia de coleta de dados

FORTE Os instrumentos de coleta de dados possuem validade **e** confiabilidade

MODERADO Os instrumentos de coleta de dados possuem validade **e** não possuem confiabilidade

FRACO Os instrumentos de coleta de dados não possuem validade **ou** a validade e a confiabilidade não são descritas

Quality Assessment Tool for Quantitative Studies



☐ Perda amostral

- ❖ As perdas foram relatadas em termos de números e / ou motivos por grupo?
- ❖ Indique a porcentagem de participantes que completaram o estudo (se a porcentagem difere por grupos, registre o mais baixo)

(80 a 100%) (60 a 79%) (menos de 60%)

Quality Assessment Tool for Quantitative Studies



☐ Perda amostral

FORTE Taxa de acompanhamento de 80% ou mais

MODERADO Taxa de acompanhamento de 60 a 79%

FRACO Taxa de acompanhamento inferior a 60% **ou** se as perdas não foram descritas

ORIGINAL ARTICLE

Effectiveness of Sucrose Used Routinely for Pain Relief
and Neonatal Clinical Risk in Preterm Infants
A Nonrandomized Study

Beatriz O. Valeri, PhD, Cláudia M. Gaspardo, PhD,*
Francisco E. Martinez, MD, PhD,† and Maria B.M. Linhares, PhD**

(Clin J Pain 2018;34:713–722)

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

- 1 Very likely
- 2 Somewhat likely
- 3 Not likely
- 4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

- 1 80 - 100% agreement
- 2 60 - 79% agreement
- 3 less than 60% agreement
- 4 Not applicable
- 5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

Sample

The convenience sample consisted of 104 preterm and very low birth weight neonates hospitalized in the NICU (level 3) of the Neonatology Service at the Clinical Hospital of Ribeirão Preto Medical School. The inclusion criteria were the following: PIs (gestational age <37 wk), with very low birth weight (<1500 g), postnatal age 14 days or below, and hospitalized in the NICU with blood collection prescribed and a consent form signed by the parents. The exclusion criteria were major congenital anomalies, intraventricular hemorrhage (grade III/IV), hyperglycemia, hypoglycemia, and the use of opioid or sedative medication or umbilical catheter in the first 2 weeks of postnatal age.

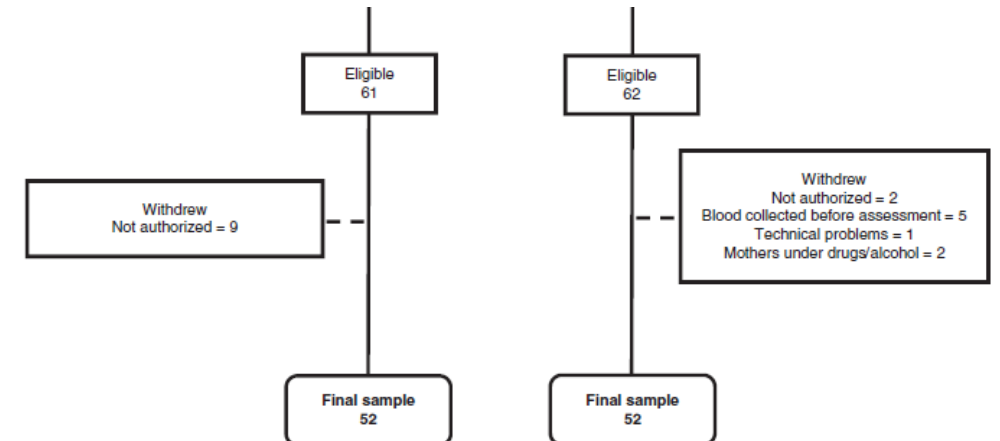


FIGURE 1. Selection of both groups of study participants. IVH indicates intraventricular hemorrhage; NICU, neonatal intensive care unit.

B) STUDY DESIGN

Indicate the study design

- 1 Randomized controlled trial
- 2 Controlled clinical trial
- 3 Cohort analytic (two group pre + post)
- 4 Case-control
- 5 Cohort (one group pre + post (before and after))
- 6 Interrupted time series
- 7 Other specify _____
- 8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

METHODS

Study Design

The study design was a nonrandomized controlled clinical trial, with a historical control group (CG).

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

- 1 Yes
- 2 No
- 3 Can't tell

The following are examples of confounders:

- 1 Race
- 2 Sex
- 3 Marital status/family
- 4 Age
- 5 SES (income or class)
- 6 Education
- 7 Health status
- 8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

- 1 80 – 100% (most)
- 2 60 – 79% (some)
- 3 Less than 60% (few or none)
- 4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

TABLE 1. Main Neonatal Characteristics, Neonatal Clinical Health Status, and Pain Context in the Groups of Preterm Infants

	Sucrose Group (n = 52)		Control Group (n = 52)		P*	P†
	1 SGHr (n = 25)	2 SGLr (n = 27)	3 CGHr (n = 22)	4 CGLr (n = 30)		
Neonatal characteristics (mean [SD; range])						
Gestational age (wk)	28.9 (± 2.4; 25-33)	30.5 (± 1.7; 27-34)	29.8 (± 1.8; 27-33)	31 (± 2; 25-33)	0.002	1 < 2*, 4†
Postnatal age (d)	7.5 (± 4; 2-14)	5.5 (± 3.4; 1-13)	4.4 (± 3.2; 2-13)	4 (± 2.6; 1-9)	0.001	1 > 3*, 4†
Birth weight (g)	933 (± 250) 580-1.445	1178 (± 169) 890-1.425	969 (± 231) 640-1.480	1214 (± 165) 880-1.490	<0.0001	1 < 2*, 4*, 3 < 2†, 4*
Male/female (f [%])	10 (40)/25 (60)	15 (56)/12 (44)	12 (55)/10 (45)	17 (57)/13 (43)	0.60	NA
SGA/AGA (f [%])	12 (48)/13 (52)	9 (33)/18 (67)	15 (68)/7 (32)	18 (60)/12 (40)	0.07	NA
Neonatal clinical health status (mean [SD; range])						
CRIB (score)	6.9 (± 2.6; 4-13)	1.8 (± 0.75; 1-3)	6.5 (± 2.2; 4-13)	1.2 (± 0.75; 0-3)	<0.0001	1 > 2*, 4*, 3 > 2*, 4*
5th min Apgar (score)	7.7 (± 2.4; 1-10)	8.7 (± 1.6; 4-10)	7.7 (± 1.6; 3-10)	8.4 (± 1.5; 5-10)	0.16	NA
Mechanical ventilation (d)	7.2 (± 4; 0-14)	3.3 (± 2.7; 0-10)	3.7 (± 2.5; 1-12)	2.9 (± 2; 0-9)	<0.0001	1 > 2*, 3†, 4*
Intubation (d)	3.8 (± 3.6; 0-13)	1.1 (± 2.4; 0-10)	1.5 (± 1.4; 0-5)	0.9 (± 1.7; 0-7)	<0.0001	1 > 2†, 3*, 4*
Medications altering HR (f [%])‡	12 (48)	10 (37)	9 (41)	13 (43)	0.88	NA
Pain context						
No. painful procedures since birth until assessment	27 (± 11; 12-57)	18 (± 9; 4-10)	24 (± 15; 8-70)	21 (± 13; 3-52)	0.06	NA
No. painful procedures per day§	4.3 (± 1.7; 2-9)	4.3 (± 2.2; 2-11)	6.2 (± 2.3-9)	5.7 (± 2.8; 2-18)	0.002	1 < 3*, 4*, 2 < 3*
No. painful procedures in the last 24 h	3.5 (± 1.7; 2-9)	3.2 (± 1.8; 1-9)	6.5 (± 2.5; 2-11)	5.3 (± 3; 0-16)	<0.0001	1 < 3†, 4*, 2 < 3†, 4*

*One-way ANOVA/ χ^2 .

†Post hoc Bonferroni.

‡Aminophylline, dobutamine, furosemide, dopamine, vancomycin, cefepime, ibuprofen, ranitidine, caffeine, terbutaline.

§Sum of painful procedures (venipuncture, arterial puncture, heel-lance, intravenous cannulation, endotracheal tube introduction, endotracheal tube suctioning, and gavage insertion for feeding) divided by postnatal age.

AGA indicates appropriate for gestational age; AVONA, analysis of variance; CGHr, control group high neonatal clinical risk; CGLr, control group low neonatal clinical risk; CRIB, Clinical Risk Index for Babies; f, frequency; HR, heart rate; NA, not applicable; SGA, small for gestational age; SGHr, sucrose group with high neonatal clinical risk; SGLr, sucrose group with low neonatal clinical risk.

*P < 0.03.

†P < 0.003.

‡P < 0.0001.

The present study had some limitations. First, the study was not randomized and blinded, as this is an inherent condition of the historical CG design. Second, the amount of sucrose that neonates had received from birth to the pain assessment day was measured indirectly by means of the number of painful procedures; the sucrose administration was estimated as there was no prescription documented in the medical/nursing chart routinely. Third, there was no control of some confounding variables presented in the 2 different time points of data collection. Fourth, HR was analyzed based on average HR, which did not show the variability pattern of the physiological indicator.

D) **BLINDING**

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

- 1 Yes
- 2 No
- 3 Can't tell

(Q2) Were the study participants aware of the research question?

- 1 Yes
- 2 No
- 3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

The present study had some limitations. First, the study was not randomized and blinded, as this is an inherent condition of the historical CG design. Second, the amount of sucrose that neonates had received from birth to the pain assessment day was measured indirectly by means of the number of painful procedures; the sucrose administration was estimated as there was no prescription documented in the medical/nursing chart routinely. Third, there was no control of some confounding variables presented in the 2 different time points of data collection. Fourth, HR was analyzed based on average HR, which did not show the variability pattern of the physiological indicator.

E)

DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

- 1 Yes
- 2 No
- 3 Can't tell

(Q2) Were data collection tools shown to be reliable?

- 1 Yes
- 2 No
- 3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

of the neonates. This instrument has been validated for PIs and tested regarding reliability and feasibility.³⁵ The following 7 facial actions were coded: brow bulge, eye squeeze, nasolabial furrow, open mouth, vertical mouth stretch, horizontal mouth stretch, and taut tongue. Each 20-second recording was divided into ten 2-second segments to be analyzed independently by 2 coders as 1 (occurred) or 0 (did not occur). In the case of >1 attempt for successful puncture for blood sampling, the NFCS was measured for the first attempt. To calculate the total score, all 7 facial actions during the 10, 2-second segments for each phase were summed, which led to a possible total score ranging from 0 to 70.³⁶ A score of 3 points was the best cut-off value for pain response, according to the discrimination between PIs undergoing a pain-related

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

- 1 Yes
- 2 No
- 3 Can't tell
- 4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

- 1 80 -100%
- 2 60 - 79%
- 3 less than 60%
- 4 Can't tell
- 5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

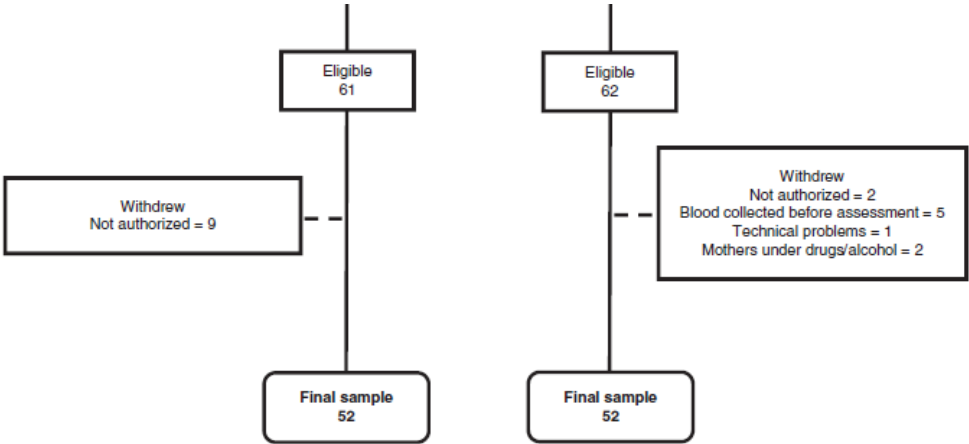


FIGURE 1. Selection of both groups of study participants. IVH indicates intraventricular hemorrhage; NICU, neonatal intensive care unit.

COMPONENT RATINGS

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E	DATA COLLECTION METHOD	STRONG	MODERATE	WEAK
		1	2	3
F	WITHDRAWALS AND DROPOUTS	STRONG	MODERATE	WEAK
		1	2	3
				Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1

2

3

STRONG
MODERATE
WEAK

(no WEAK ratings)
(one WEAK rating)
(two or more WEAK ratings)

Developmental Care Approaches for Mitigating Stress in Preterm Neonates in the Neonatal Intensive Care Unit: A Systematic Review

Nathália de Figueiredo Silva, Maria Beatriz Martins Linhares,
and Cláudia Maria Gaspardo
University of São Paulo

The aim of the present study was to perform a systematic review of the impact of developmental care approaches on indicators of stress in preterm neonates who were admitted to the neonatal intensive care unit (NICU). Twenty-two studies were identified in the PubMed, Web of Science, PsycINFO, and SciELO databases using the keywords “preterm neonates,” “stress,” and “developmental care.” The methodological quality of the studies was assessed according to the Effective Public Health Practice Project tool. Nine developmental care approaches were employed for preterm infants similarly to the approaches that are employed in the NICU environment. Positive results with regard to physiological and behavioral indicators of neonatal stress were identified. However, negative results were also found with regard to higher levels of stress as a physiological indicator. With regard to the methodological quality of the studies, 54% were classified as having moderate quality, and 46% were classified as having either strong (23%) or weak (23%) quality. These findings suggest that there is growing interest in developing developmental care approaches to minimize stress in hospitalized preterm neonates, but no consensus has been reached regarding the measures that are used to assess stress. Most interventions are in the exploratory stage, with little methodological convergence. Future studies are needed that integrate the assessment of both physiological and behavioral measures of neonatal stress and seek to validate developmental care approaches that are already used in the NICU based on scientific evidence.

Keywords: neonatal intensive care unit, prematurity, stress, developmental care, systematic review

Table 4
Methodological Quality Assessment Analysis of the Studies Based on the Effective Public Health Practice Project Tool

Reference	Selection bias	Design	Confounders	Blinding	Data collection methods	Withdrawals and dropouts	Overall rating
Lyngstad et al. (2014)	↑	RCT	Yes	Undetermined	Yes/Yes	Yes	Strong
Chang et al. (2002)	↓	RCT	Yes	Undetermined	Yes/Yes	Yes	Strong
Comaru & Miura (2009)	↑	RCT	Yes	Yes	Yes ^a /Yes	Yes	Strong
Mitchell, Yates, Williams, & Hall (2013)	↑	RCT	Yes	Undetermined	Yes/Yes	Yes	Strong
Aita et al. (2013)	↑	RCT	Yes	Yes	Yes/Yes	Yes	Strong
Lacina et al. (2015)	↓	RCT	Yes	Yes	Yes ^a /Yes	Yes	Moderate
Byers, Lowman, et al. (2006)	↑	Other	Yes	Undetermined	Yes/Yes	Yes	Moderate
Mitchell, Yates, Williams, Chang, et al. (2013)	↓	CCT	Undetermined	Undetermined	Yes/Yes	Yes	Moderate
Cone et al. (2013)	↓	CCT	Yes	Undetermined	Yes ^a /Yes	No	Moderate
Kleberg et al. (2008)	↑	RCT	Yes	No	Yes ^a /Yes	Yes	Moderate
Field et al. (2006)	↑	CCT	Yes	Yes	Yes ^a /Yes	No	Moderate
Hernandez-Reif et al. (2007)	↑	CCT	Yes	Yes	No ^a /No	Yes	Moderate
Bertelle et al. (2005)	↑	CCT	Yes	Undetermined	Yes/Yes	No	Moderate
Dieter et al. (2003)	↑	CCT	Yes	Undetermined	Yes ^a /Yes	Yes	Moderate
Touch et al. (2002)	↑	CCT	Yes	Yes	Yes/Yes	No	Moderate
Alipour et al. (2013)	↑	CCT	Undetermined	Yes	Yes/Yes	Yes	Moderate
Feldman & Eidelman (2003)	↑	C-C	Yes	Undetermined	Yes/Yes	No	Moderate
Schwilling et al. (2015)	↑	Other	Undetermined	Undetermined	Yes/Yes	No	Weak
Rand & Lahav (2014)	↑	Not stated	Yes	Undetermined	Yes/Yes	No	Weak
Im et al. (2009)	↑	CCT	Yes	No	Yes/Yes	No	Weak
Whitley & Rich (2008)	↑	CCT	Yes	Yes	Undetermined/Undetermined	Yes	Weak
Smith et al. (2013)	↑	RCT	Yes	Undetermined	Yes/Yes	Undetermined	Weak

Note. RCT = randomized clinical trial; CCT = controlled clinical trial; C-C = case-control; Other = design not stated by tool; ↑ = very likely; ↓ = somewhat likely.

^a Instrument in exploratory stage.

Lahav, 2014; Schwilling et al., 2015; Touch et al., 2002), and the reporting of this information was incomplete in one study (Smith et al., 2013).

Most of the studies evaluated herein (54%) presented an overall rating of moderate methodological quality, followed by 23% of the studies with strong methodological quality and 23% with low methodological quality.

Discussion

The studies that were analyzed in the present systematic review investigated the impact of

Most of the studies reviewed herein were classified with moderate or strong methodological quality. Notably, the authors of these studies performed controlled and randomized clinical trials. Among the components of assessment of methodological quality, confounding factors and methods of data collection were the most contemplated components, and withdrawals and dropouts were the least considered by the studies.