**Postural Control Measurements to Predict Future Motor Impairment in Preterm Infants: A Systematic Review**

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**ABSTRACT**

**Background:** There is a risk of motor impairment in all preterm infants born at <37 weeks gestation. Preterm infants demonstrate a lower quality of spontaneous movements, are more likely to display abnormal fidgety movements, and are more likely to demonstrate body and head asymmetry compared to term infants. Postural measurement tools, including portable pressure-sensitive mats and force plates, may be effective in measuring COP in preterm infants.

**Objective:** The purpose of this review was to evaluate the existing evidence regarding the use of pressure mats or force plates to measure postural control and movement in preterm infants. We also evaluated how those measures differ in preterm and full-term infants and how these differences may predict future motor impairment or disability in this population.

**Methods:** The databases consulted were PubMed, Embase, Scopus, and CINAHL. The study included cross-sectional studies, prospective observational cohort studies, and a case study. The quality of literature and risk of bias was rated utilizing the ROB2: revised Cochrane risk-of bias tool for randomized trials.

**Results:** Eight manuscripts were included. The postural control tools and choice of measurements included were the FSA UltraThin seat mat, the Conformat Pressure-Sensitive mat, the Play and Neuro-Developmental Assessment, and standard force plates. He studies showed that all tools were capable of assessing COP in preterm infants.

**Conclusions:** Postural measurement tools such as force plates and pressure sensitive mats

provide a quick, accurate, and objective measure of COP and asymmetry, and, based on the

degree of severity in postural control and movement, may provide an alternative to application of

standardized assessments that may be time-intensive, taxing to the preterm infant, inaccessible to

therapists, or potentially not sensitive enough to capture motor delays.

**Keywords:** postural control, center of pressure, preterm, force plate, infant, disability, measurement

The authors report there are no competing interests to declare.

**Introduction**

There is a risk of motor impairment in all preterm infants born at <37 weeks gestation, however, the risk is highest in infants born moderately preterm (32-34 weeks gestation) at 20.6% and very preterm (<32 weeks gestation) at 36.1%.1,2 Risk of motor impairment in full-term infants ranges from 2-7% compared to 54-64% in preterm infants.3 There are notable differences in the movement patterns of preterm infants as compared to full-term infants. Preterm infants demonstrate a lower quality of spontaneous movements compared to term infants, described as lower fluency, less variability, and impaired sequencing.4 Furthermore, preterm infants are more likely to display abnormal fidgety movements, which are often jerky or stiff, while term infants demonstrate both fidgety and smooth movements in their motor repertoire.5,6 Preterm infants also demonstrate decreased postural complexity, defined as the use of a variety of postural control strategies, as compared to healthy term infants.7

Preterm infants are more likely to display body and head asymmetry and show preference for extension patterns than full-term infants.6 These asymmetrical patterns may be attributed to the development of increased power in the extensor muscle groups in preterm infants. This increased muscle power, which can be described as spontaneous motility, symmetry in arms, shoulders, trunk, and legs, and active adjustments in the trunk,8 results in the hyperextended posture commonly observed in preterm infants, and contributes to the difficulty these infants have maintaining midline orientation.8,9

The neonatal intensive care unit (NICU) environment is not optimal for neonatal growth and development as a result of a variety of environmental conditions including noise, lights, noxious stimuli, and suboptimal musculoskeletal support.10 Preterm infants are vulnerable to the effects of gravity on alignment, posture, mobility, respiratory abilities, and shaping of the musculoskeletal system.11,12 At 24 weeks gestation, preterm infants demonstrate incomplete development of muscle tissue and muscle tone, as well as boney structures like the vertebral column.11 Without the intrauterine environment facilitating a flexed posture and limiting extremity movement, preterm infants succumb to the weight of gravity and begin to favor an extended posture. Instead of experiencing graded resistance from the uterine walls as the fetus moves in and out of flexion, preterm infants often extend their trunk and extremities further into the flat surface they are placed upon, potentially in an attempt to gain postural stability,11,12 resulting in commonly described postures of exaggerated cervical lordosis and hyperextension.11 The combination of gravity and hyperextension leads to weak and overstretched muscles of the anterior neck and trunk, interferes with purposeful self-soothing movements directed towards the midline, and contributes to developmental delay.11,12

Extended posture and associated asymmetries in movement can result in head or positional preferences. The prevalence of such positional asymmetries range from 45 to 79% of preterm infants.13,14 Head turn preferences in preterm infants are associated with sub-optimal reflexes, decreased maturation of gross motor movements, and the development of torticollis and deformational plagiocephaly during infancy.13,14 These impairments if not fully addressed, further contribute to delays with increasing infant age, including impaired fine motor skills, asymmetrical gait patterns, and postural asymmetries.14,15

As noted above, moderate to severe neuromotor and sensory disabilities are highly prevalent in extremely and very preterm infants born between 22-34 weeks gestation,16 requiring early assessment and intervention. Preterm infants born at 24 to 31weeks gestation remain in the Neonatal Intensive Care Unit (NICU) for a range of 34-123 days.17 Due to increased risk of motor delay, these infants often receive physical, occupational, and speech therapy services during hospitalization. Current evidence supports parent and therapist delivered motor intervention to improve motor and cognitive development and outcomes in preterm infants,18 and immediate, ongoing therapy services after hospital discharge to reduce the risk of developmental delays; however, there is often a delay in therapy services after NICU discharge,19,20 especially if no significant motor impairment or diagnosis is documented using a standardized or objective measure. The increased risk for developmental impairment in preterm infants demonstrates the need for a measure for future motor delay in order to provide timely, appropriate therapy services. Standardized motor assessments are essential to documenting delay and identifying impairments that may respond to targeted intervention. These assessments vary based on appropriate age for administration, domains of function tested (ex. motor, neurobehavior) and indications, applications, and predictive validity, but few standardized assessments are sensitive enough to decrease the gap in qualification for early therapy-based intervention.21,22 The assessments also vary greatly by administration requirements with many necessitating costly training programs to learn and administer testing.23 While these programs are in place for the essential purpose of ensuring reliable and valid results for clinical and research applications, the rigorous requirements are often out of reach for therapists and the units they serve due to lack of continuing education funds and resources. In the absence of extended time for clinicians to attend training programs and funding to pay for such programs, it is prudent to identify objective measures that indicate potential delay that can be used, assessed, and understood by a variety of clinicians and researchers. Quantitative measurements such as center of pressure (COP) and variability of movement have been shown to be predictive of motor impairment or delay in preterm infants,24 but these measures are not currently used in the clinical setting to identify infants at risk for movement delay.

 Postural measurement tools, including portable pressure-sensitive mats and force plates, may be effective in measuring COP in preterm infants. Quantitative measurements from these tools indicating atypical postural movement patterns have been associated with the development or lack of development in infant motor abilities. The purpose of this review was to evaluate the existing evidence regarding the use of pressure mats or force plates to measure postural control and movement in preterm infants. We also evaluated how those measures differ in preterm and full-term infants and how these differences may predict future motor impairment or disability in this population.

**Methods**

***Eligibility Criteria***

The following inclusion criteria were used to select studies: 1) articles that include infants born at or prior to 37 weeks, 2) measurements were collected in supine, 3) measurements were collected using a pressurized mat or mattresses, and 4) articles were in reference to humans. Exclusion criteria included: 1) based on infants born after 37 weeks gestation, 2) measurements were measured in positions other than supine, or 3) articles with reference to animals. We did not include gray literature or dissertations.

***Data Sources and Search Strategy***

The protocol for the review was drafted using the Preferred Reporting Items for Systematic Reviews and Meta-analysis Extension for scoping reviews (PRISMA-ScR)25 and was registered to PROSPERO and the Open Science Framework (OSF)26. The objective of this scoping review was to answer the question: “In preterm infants, can Center of Pressure measurements and variability of movement measurements in supine help determine the risk of motor delay in infancy?”. A search strategy using keywords was developed by the primary author (JB) in consultation with a university librarian and included “("Infant, Newborn" [MeSH] OR "Premature Birth" [MeSH] OR Neonatal [tiab]) AND ("Postural Balance"[MeSH] OR "Pressure, Mat\*" [tiab] OR "Multisensor" [tiab] OR "Force Plate" [tiab])”. Four databases were searched in September 2022 (PubMed, Embase, Scopus, and CINAHL). One investigator (JB) used MeSH headings and text words to complete the search. Results were imported to Covidence27, a systematic review production tool for title/abstract/full-text review and data abstraction.

***Data Extraction***

Two reviewers (JB, SK) independently reviewed and extracted papers that met inclusion criteria for full text review through methods consistent with the PRISMA guidelines28. Any disagreement about inclusion was discussed amongst all authors (JB, SK, DM) and the senior author (DM) made the final determination. Papers that passed full-text review were evaluated with an extraction table based on recommendations from the Cochrane Collaboration29 and included the following characteristics: study aims, study design, data sources, study population, outcome measures, data analysis strategy, postural measurement tool, results, implications, strengths, and limitations. Data extracted were then reviewed using a descriptive approach to summarize key findings.

***Quality Assessment***

The quality of literature and risk of bias was rated utilizing the ROB2: revised Cochrane risk-of-bias tool30 for randomized trials for each included study (See Table 2). Independent assessment was completed by two reviewers (JB and DM), and full agreement was reached after discussion.

**Results**

***Study Selection***

 The initial keyword search identified nine hundred articles. Two-hundred and fifty-three of these were excluded as duplicate articles from multiple data bases. The remaining six-hundred and forty-seven articles underwent a title and abstract screen based on the inclusion and exclusion criteria. Full-text review for eligibility was completed for twenty-five full text studies, and eight met all eligibility criteria. (Figure 1.)

***Characteristics of the Included Literature***

Of the included articles, 5 were prospective cohort studies7,24,31-33, 2 were cross-sectional studies34,35, and 1 was a case study36. Characteristics of these studies are noted in Table 1. All studies were conducted in the United States7,24,31,34-36 or Norway32,33.

***Participants***

 All of the studies included infants born preterm (< 37 weeks of gestation).7,24,31-36 The majority of studies also included a control group of full-term infants with typical motor control. (See Table 1) 1.7,24,32-35 The pre-term infants included in these studies had an average birthweight of 1,124.5 g +/- 449.32 grams.7,24,31-36 No other participant characteristics were shared within the selected studies.

***Quality Assessment***

 The results of the quality assessment can be seen in Table 2. Only 1 study was determined to be of overall high concern for bias when using the RoB:2 revised Cochrane risk-of-bias tool.30 Due to the nature of our infant population and prognostic study, blinding was not achieved, and random allocation did not occur in all studies. This led to all 8 studies being rated “high concern” for domain 1. Two studies32,33 also received “high concern” in other domains due to deviation from intended intervention32,33 and missing outcome data32.

***Postural Control Measurement Systems and Synthesis of Motor Outcomes***

*Types of Measurement Tools*

Postural control tools and choice of measurement varied between studies as seen in Table 1. Two studies utilized the FSA UltraThin seat mat34,35 to measure the maximum pressure value34, the ratio of head and pelvis to trunk pressure34, and COP.34,35 The Conformat Pressure-Sensitive mat was utilized in three studies7,31,36 to measure COP31,36, magnitude and complexity of movement7,36,head control7,36, and reaching ability7,36. The Play and Neuro-Developmental Assessment (PANDA) gym24 was used to measure limb and trunk kinematics and COP measurements.24 Lastly, two studies used standard forceplates32,33 to measure postural adjustments to reach and the displacement of COP.32,33

*FSA UltraThin Seat Mat*

The FSA UltraThin seat mat is a pressure-sensitive mat that is commonly used in wheelchair seating systems. FSA stands for Force Sensing Array and includes a 4D pressure mapping system.37 Measurements include total duration of trunk flexion, extension, or neutral positioning, determined by the total number of frames the infant’s trunk was in each position and multiplying the total consecutive frames by the sampling period (200 msec)35; approximate entropy, a ratio that estimates the randomness, fluctuation, and unpredictability of time-series of data38; and root mean square values, the standard deviation of the displacement of the COP in the caudal-cephalic and medial-lateral directions.34,39

Results showed that term infants spent significantly more than 2/3 of the awake segment in flexion or neutral (p=0.027), whereas preterm infants did not (p =1.52).35 This further supports previous evidence that preterm infants lack physiological flexion due to the forces of gravity and lack of movement against the uterine wall.40 It was also found that preterm infants exhibited larger root mean square values (p=0.01) and smaller approximate entropy values (p=0.02) in the caudal-cephalic direction than infants born of term.34 The smaller approximate entropy and larger root mean square values suggest less complex, repetitive movement, and less stable posture in the caudal-cephalic direction in preterm infants.34

*Conformat Pressure-Sensitive Mat*

A Conformat Pressure-Sensitive mat is a portable and lightweight seating and positioning system often used for wheelchair pressure mapping, that provides information on pressure distribution and center of force trajectory.41 Dusing et al. used the Conformat Pressure-Sensitive mat to measure the root mean square and approximate entropy values (as defined in the previous section) in the caudal-cephalic and medial-lateral directions.7,31,36

Meaningful results from this study showed a significant interaction between condition and age, in the caudal-cephalic direction of postural variability (p=0.03). It was also determined that root mean square was significantly lower at 4 and 5 months of age in the toy condition (p=0.01), indicating low complex movements in the caudal-cephalic direction for preterm infants.36 Importantly, this result demonstrates that decreased postural complexity before the development of midline head control or reaching may be an indication of future motor delay.7

*The PANDA Gym*

PANDA, the Play And NeuroDevelopmental Assessment, includes an array of toys with sensors in them, a camera-based computer vision system, and a mat structure covered in carbon fiber.24 This gym also includes a PVC pipe above the platform to suspend toys from and support the video system.24 The PANDA gym measured 7 variables including PathLength, the total distance an object moved from its initial position to its final position; ExcursionX/Y, with ExcursionX being the farthest distance in the medial-lateral direction, or side-to side shifting and ExcursionY being the farthest distance in the caudal-cephalic direction, or vertical shifting.24; and ElipseArea, the scatter of COP in the X and Y directions.24,42

It was determined that vertical displacement (ExcursionY) was significantly lower in the preterm group compared to the full term group (difference = 3.65 cm, 95% confidence interval (CI): 0.13–7.17 cm, p = 0.043), demonstrating a smaller distance traveled in the caudal-cephalic direction, with minimal vertical shifting.24  The COP variability (EllipseArea) was significantly lower in the preterm vs full-term group (difference = 2.3 cm, 95% CI: 1.06–4.84 cm, p = 0.038).24 These results show that there was less variability of movement in the preterminfants,specifically in the caudal-cephalic direction. The total distance traveled (PathLength) was significantly higher in the preterm group compared to the full term group for 3 conditions (no toy 153.4 vs. 101.3 cm, p = 0.0054; orangutan—bilateral reach 146.1 vs. 87.5 cm, p = 0.0088; and elephant—unilateral reach 176.6 vs. 112.2 cm, p = 0.0005), demonstrating increased movement from initial position to final position in preterm infants.24 Lastly, PathLength was found to be higher in the group that was later identified as having impaired motor control, in all conditions (no toy 155.6 vs. 115.9 cm, p = 0.033; orangutan—bilateral reach 158.4 vs. 100.1 cm, p = 0.003, and elephant—unilateral reach 223.1 vs. 122.2 cm, p < 0.0001).24

*Force Plates*

An Anti or Kistler force plate is a multi-axis force plate typically used in high-performance sports.43,44 These force plates are capable of measuring all dynamic motion sequences including any abruptly changing forces.43 In two studies32,33, total body COP from force plates was analyzed in several different ways including PathLength (as defined above), length and duration of movement path/time, number of directional changes in COP displacement, and maximum velocity: the maximum speed in which the infant moves in the cranial-caudal and medial-lateral directions.32,33,45

Findings from the force plate data showed that at 4 months, a lower maximum velocity of COP and smaller displacement of COP in the medial-lateral direction was related to coordination problems (p=0.04). At 4 and 6 months, performance on the movement ABC that was scored below the 15th percentile was associated with lower Vmax of COP in the medial lateral direction (p=0.02, p=0.03) and a lower number of cranial-caudal oscillations (p=0.02, p=0.01).33 Further, total body COP in preterm infants differed from that of full-term infants with a smaller distance travelled by the COP during reaching in both the cranial-caudal and medial-lateral directions, demonstrating relatively immobile postural behavior.32

**Discussion**

While there is still much to learn about quantitative measurement of postural control in preterm infants, available evidence demonstrates that tools such as force plates and pressure mats may be feasibly used for measurement of infant postural control and asymmetry.7,24,31-36 Further, these tools identified differences in preterm infant movement as compared to full term infant movement. Quantitative measurements of trunk positioning during spontaneous activity may be a reasonable and useful measure to identify infants at high risk for motor impairment or disability and those who are not.24,35

Fallang et al. compared COP measurements at 4 and 6 months with the Movement Assessment Battery for Children (ABC) at the age of 6 and determined that immobile postural behavior at 6 months was associated with a worse score on the movement ABC.32,33 Further, a lower Vmax of COP in the medial-lateral direction (p=0.02) and a lower number of oscillations in the cranial-caudal direction (p=0.02) was correlated with performance below the 15th percentile on the movement ABC.33  This study in particular clearly demonstrates the correlation between infant postural behavior and the development of motor impairment.

Postural measurements have been informative in research, but the results from this systematic review demonstrate a potential for clinical application in order to aid in early identification of infants with motor delay. Specific atypical measurements of postural control that have been associated with future motor impairment include COP pathlength, COP extent, variety of movement, and speed of movement, especially in the caudal-cephalic direction.24,34 Preterm infants that demonstrate large and predictable COP movement in the caudal-cephalic direction, a relatively immobile posture, a lack of successful reaching by 4 months, and inadequate reaching quality at 6 months in supine are sensitive markers for less optimal motor development.32,33,34

Currently, many infants do not qualify for early intervention services when assessed by Part C of the Individuals with Disabilities Education Improvement Act.7 Additionally, available standardized assessments may not be sensitive enough to capture the extent of an infant’s delay because they quantify the infant’s capacity to exert postural control in specific developmental positions, but do not quantify the quality infant’s movement.21,46 For example, Wang et al. discusses that the General Movement Assessment can identify absent or fidgety movement but a limitation of this assessment is that the measurement tool used to quantify such movement did not exist.21 The Motor Optimality Score (MOS), a detailed scoring of the GMA, is currently in early stages of reliability testing but requires advanced GMA certification to administer.47 Several studies also support the idea that complexity, trajectory, area, and velocity of COP are good predictors of typical development, with one stating that absence of fidgety movement at 3 months is the greatest prognostic value for predicting motor impairment.21,48

***Limitations of this Study***

Limitations of this study include the acknowledgement that use of pressure-sensitive mats and force plates in the clinical setting may not be easily attained due to the high cost of equipment and maintenance requires; however, with more advanced technology, newer devices are becoming available that increase affordability and portability for clinical spaces. We also acknowledge that a shift in practice would be necessary to use atypical postural control measurements to quantify motor delays. Furthermore, clinicians would need additional training to collect and interpret this data in a meaningful and objective way.

***Implication for Future Research***

This study provides ample evidence for the use of pressure mats and force plates to measure postural control and variability of movement in preterm infants, but future research is needed to employ this globally. Future research should focus on the validity, predictive ability, sensitivity to change over time, and quantification of severity necessary to detect future motor impairments.24 Further, infants should be assessed over a shorter time period to improve test-retest reliability of this method.31 A longitudinal follow up of high risk infants and those who go on to have disabilities may also be useful in determining infants ability to adapt to changing task demands based on postural control in early infancy.4 The studies presented in this systematic review show evidence that reduced postural complexity before development of midline head control may indicate future motor delay.7,31,34,36 This should be verified utilizing a larger sample size with a longer follow-up in the future.7 Future research is also necessary in determining if there are critical periods of time in which postural complexity has a larger impact on development, optimal variability, and whether physical therapy intervention can modify this.34,36 Based on risk of bias assessment for manuscripts assessed in this study, blinding of researchers or separation of tasks for collecting and reducing the data should be considered in the methodology of future studies.35

***Conclusions***

There is a need to identify impairments in early postural and movement complexity in order to avoid delays in therapy services, and to provide informative interventions used to promote postural control and spontaneous movement.7,31 Altered posture and movement in preterm infants limits the infant’s ability to explore the world around them, perform variable movements, use perceptual information to modify movement, and practice a variety of postural control strategies.31,36 Postural measurement tools such as force plates and pressure sensitive mats provide a quick, accurate, and objective measure of COP and asymmetry, and, based on the degree of severity in postural control and movement, may provide an alternative to application of standardized assessments that may be time-intensive, taxing to the preterm infant, inaccessible to therapists, or potentially not sensitive enough to capture motor delays.

**Appendix**

Figure 1: Study selection process



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| --- |
| Table 1. Study Characteristics |
| First author, year | Aim | Study Design | Study Population | Postural Measurement Tool  | Outcome  |
| Dusing, Kyvelidou, Mercer, Stergiou 2009 | To determine whether infants born at full term and infants born preterm differ in their COP movement variability characteristics, evaluated both linearly and nonlinearly while positioned supine. | Cross-Sectional Study | (47%) born full term | FSA UltraThin Seat Mat | Infants born pre-term exhibited larger root-mean-squared values in the caudal-cephalic direction than infants born full-term. |
| Dusing, Mercer, Yu, Reilly, Thorpe 2005 | To compare trunk position in supine of infants born preterm and at term. A secondary purpose was to determine the feasibility of using pressure data to assess trunk position. | Cross-Sectional Study | (45%) born full term | FSA UltraThin Seat Mat | Infants born preterm differ in their trunk positions immediately after birth as demonstrated by decreased time spent in flexion or neutral. |
| Dusing, Thacker, Galloway 2016 | To fill knowledge gaps on the development of adaptive postural control in infants born preterm | Cohort Study (Prospective Observational Study) | (0%) born full term | Conformat Pressure-Sensitive Mat | Infants born preterm did not alter the postural variability in the caudal-cephalic direction in response to a visual stimulus prior to 4 months of age. They were able to adapt postural variability in the medial lateral direction at 2.5 months of age. |
| Dusing, Izzo, Thacker, Galloway 2014A | To investigate group differences in postural variability between infants born preterm and at risk for developmental delays or disability and infants born full term with typical development, during the emergence of early behaviors  | Cross-Sectional Study | (55%) born full term | Conformat Pressure-Sensitive Mat | Measures of early postural complexity are helpful in the development of interventions during the first months of life to prevent the delay in postural control strategies in preterm infants. |
| Dusing, Izzo, Thacker, Galloway 2014B | To describe how changes in postural control during development may relate to action and perception in 3 infants born preterm with brain injury  | Case Study | (0%) born full term | Conformat Pressure-Sensitive Mat | Excessive postural complexity and reduced postural complexity alter the infants’ abilities to act on the world around them and use perceptualinformation to modify their actions. |
| Fallang & Hadders-Algram 2005 | To discuss the clinical and neurophysiological data of postural behavior  | Cohort Study (Prospective Observational Study)  | (25%) born full term | Force plate | Total body COP in preterm infants differs markedly from that of full terms. Preterm infants show a relatively immobile postural behavior and maximum velocity of COP was substantially lower than full-term infants. |
| Fallang, Oien, Hellem, Didrk, Saugstad, Hadders-Algra 2005 | To investigate whether parameters of nonoptimal reaching and reduced COP behavior at an early age are associated with dysfunctional neuromotor and behavioral development at school age.  | Cohort Study (Retrospective Observational Study) | (19%) born full term | Amti or Kistler Force plate | I n preterm infants who do not develop CP, a lack of successful reaching at 4 mo and aninadequate quality of reaching at 6 mo (corrected age) aresensitive markers of clinically significant forms of brain dysfunction, such as complex MND. |
| Prosser, Aguirre, Zhao, Bogen, Pierce, Nilan, Zhang, Shofer, Johnson 2021 | To investigate the ability of biomechanical measures of early postural control to distinguish infants with future impairment in motor control. | Cohort Study (Prospective Observational Study) | 53%) born full term | Play and Neuro-Developmental Assessment (PANDA) gym  | Quantitative methods of measuring postural control in infants born preterm and who are still hospitalized are feasible and show promise for early detection of motor impairment. |

Table 2: Quality assessment utilizing the ROB2: revised Cochrane risk-of bias tool

|  |  |
| --- | --- |
| **ROB 2 Quality Ratings**  | **Articles**  |
| **Areas of Quality Assessed**  | Dusing, Izzo, Thacker, Galloway 2014 B  | Dusing, Thacker, Galloway, 2014 A | Dusing, Kyvelidou, Mercer, Stergiou, 2009  | Dusing, Thacker, Galloway, 2016  | Dusing, Mercer, Yu, Reilly, Thorpe, 2005  | Fallang, Hadders-Algra, 2005  | Fallang, Oien, Hellem, Saugstad, Hadders-Algra, 2005  | Prosser, 2022  |
| 1.1 Was the allocation sequence random?   | N  | N  | N  | N  | N  | N  | N  | N  |
| 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?   | N  | N  | N  | N  | N  | N  | N  | N  |
| 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?   | PY  | N  | N  | N  | PY  | NI  | N  | PY  |
| Domain 1 Risk-of-bias-judgement: Risk of bias arising from the randomization process  | High Concern  | High Concern  | High Concern  | High Concern  | High Concern   | High Concern  | High Concern  | High Concern  |
|   |
| 2.1 Were participants aware of their assigned intervention during the trial?   | N  | N  | N  | N  | N  | N  | N  | N  |
| 2.2 Were carers and people delivering the intervention aware of participants’ assigned intervention during the trial?   | Y  | Y  | Y  | Y  | Y  | Y  | Y  | Y  |
| 2.3 if Y/PY to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?   | N  | N  | NA  | Y  | NA  | N  | Y  | N  |
| 2.4 if Y/PY to 2.3: Were these deviations likely to have affected the outcome?   |   |   |   | PY  |   |   | PY  |   |
| 2.5 if Y/PY to 2.4: Were these deviations from intended intervention balanced between groups?  |   |   |   | NA  |   |   | NI  |   |
| 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?  | PY  | Y  | Y  | NA  | Y  | NI  | N  | Y  |
| 2.7 If N/PN to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyze participants in the group to which they were randomized?  |   | NA  |   | NA  |   | Y  | Y  |   |
| Domain 2 Risk-of-bias-judgement: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)  | Low Concern  | Low Concern   | Low Concern  | Some Concern  | Low Concern  | High Concern  | High Concern  | Low Concern  |
|   |
| 2.1 Were participants aware of their assigned intervention during the trial?  | N  | N  | N  | N  | N  | N  | N  | N  |
| 2.2 Were carers and people delivering the interventions aware of the participants’ assigned intervention during the trial?   | Y  | Y  | Y  | Y  | Y  | Y  | Y  | Y  |
| 2.3 [if applicable] If Y/PY to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?  | NA  | Y  | Y  | NA  | Y  | NI  | NA  | NI  |
| 2.4 [if applicable] Were there failures in implementing the intervention that could have affected the outcome?  | NA  | Y  | PY  | PY  | NA  | NI  | NA  | Y  |
| 2.5 [if applicable] Was there non-adherence to the assigned intervention regimen that could have affected participants’ outcomes?  | NA  |   | N  | PY  | Y  | NI  | NA  |   |
| 2.6 if N/PN to 2.3 or Y/PY to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?   | NA  | NA  | NA  | N  | NA  | NI  | NA  | Y  |
| Domain 2 Risk-of-bias-judgement: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)  |    Low Concern  | Low Concern   | Low Concern   | Some Concern  | Low Concern  | High Concern  | Some Concern  | Some Concern  |
|   |
| 3.1 Were data for this outcome available for all, or nearly all, participants randomized?   | N  | N  | Y  | N  | N  | NI  | N  | N  |
| 3.2 If N/PN to 3.1: is there evidence that the result was not biased by missing outcome data?   | N  | N  | NA  | PY  | N  | N  | N  | N  |
| 3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?  | N  | N  | NA  | PY  | N  | Y  | N  | Y  |
| 3.4 If Y/PY to 3.3: Is it likely that missingness in the outcome depended on its true value?   |   |   | NA  | PY  |   | NI  |   | N  |
| Domain 3 Risk-of-bias-judgement: Missing outcome data  | Low Concern  | Low Concern  | Low Concern  | Some Concern  | Some Concern  | High Concern  | Some Concern  | Some Concern  |
|   |
| 4.1 Was the method of measuring the outcome inappropriate?   | N  | N  | N  | N  | N  | N  | N  | PN  |
| 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?  | N  | N  | N  | NA  | NA  | N  | N  | N  |
| 4.3 If N/PN to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?   | Y  | NA  | Y  | Y  | NA  | Y  | Y  | NI  |
| 4.4 If Y/PY to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?  | N  |   | NA  | N  | NA  | N  | PN  | NA  |
| 4.5 if Y/PY to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of the intervention received?  |   |   | NA  |   |   |   | PY  | NA  |
| Domain 4 Risk-of-bias-judgement: Risk of bias in measurement of the outcome  | Low Concern  | Low Concern  | Low Concern  | Low Concern  | Low Concern  | Low Concern  | Some Concern  | Low Concern  |
|   |
| 5.1 Were the data that produced this result analyzed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?   | Y  | Y  | Y  | Y  | Y  | N  | Y  | Y  |
| Is the numerical result being assessed likely to have been selected, on the basis of the results from:   |   |
| 5.2 multiple eligible outcome measurements within the outcome domain?  | NI  | NI  | NI  | NI  | NI  | NI  | Y  | NI  |
| 5.3 multiple eligible analyses of the data?   | NI  | NI  | NI  | NI  | NI  | NI  | Y  | NI  |
| Domain 5 Risk-of-bias-judgement: Risk of bias in selection of the reported result  | Low     Concern   | Low Concern   | Low Concern  | Low Concern  | Low Concern  | High Concern  | Some Concern  | Some Concern  |
|   |
| **Overall Risk of Bias**  | Low     Concern  | Some Concern  | Low Concern  | Some Concern  | Some Concern  | High Concern  | Some Concern   | Some Concern  |

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