

Table F-4. Key findings in studies of specialized diets

<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years \pm SD</p> <p>Mean IQ \pmSD</p>	<p>Outcome measure/Baseline scores, mean \pmSD</p>	<p>Outcome measure/Post- treatment scores, mean \pm SD</p>
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<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
<p>Hyman et al., 2016⁵⁰ RCT</p> <p>Gluten-free/casein-free diet followed by weekly challenges of gluten, casein, gluten and casein and placebo G1: gluten G2: casein G3: gluten and casein G4: placebo Crossover study n=14</p> <p>12 weeks/EOT</p> <p>Low RoB</p>	<p>Age 3.78 ± 0.60</p> <p>IQ NR</p>	<p>LS means</p> <p>Day before challenge</p> <p>Conners- research asst rater G1: 6.65 ± 2.38 G2: 5.71 ± 2.18 G3: 5.32 ± 2.13 G4: 6.17 ± 3.01</p> <p>Conners- teacher G1: 8.50 ± 3.72 G2: 8.29 ± 3.73 G3: 6.89 ± 2.40 G4: 8.84 ± 5.92</p> <p>Conners- parent G1: 6.10 ± 3.53 G2: 6.48 ± 3.99 G3: 5.79 ± 4.17 G4: 5.71 ± 3.50</p> <p>Day before challenge: NR</p> <p>Day of challenge</p> <p>Sensory motor G1: 0.34 ± 0.27 G2: 0.32 ± 0.28 G3: 0.31 ± 0.37 G4: 0.33 ± 0.30</p> <p>Social relationships G1: -0.30 ± 0.24 G2: -0.30 ± 0.21 G3: -0.27 ± 0.17 G4: -0.20 ± 0.16</p> <p>Affectual relationships G1: 0.08 ± 0.12 G2: 0.09 ± 0.13 G3: 0.05 ± 0.11 G4: 0.09 ± 0.11</p> <p>Sensory responses G1: 0.25 ± 0.14 G2: 0.26 ± 0.19 G3: 0.21 ± 0.14 G4: 0.30 ± 0.19</p> <p>Language G1: -0.07 ± 0.31 G2: -0.04 ± 0.27 G3: -0.03 ± 0.30</p>	<p>EOT</p> <p>LS means</p> <p>Day after challenge</p> <p>Conners- research asst rater G1: 5.57 ± 1.61 G2: 6.19 ± 2.47 G3: 6.73 ± 3.24 G4: 6.55 ± 2.83 p=ns</p> <p>Conners- teacher G1: 7.76 ± 3.08 G2: 7.42 ± 2.79 G3: 7.19 ± 2.81 G4: 7.43 ± 3.88 p=ns</p> <p>Conners- parent G1: 6.75 ± 3.69 G2: 6.31 ± 3.75 G3: 7.15 ± 4.42 G4: 7.15 ± 4.25 p=ns</p> <p>Day after challenge</p> <p>Sensory motor G1: 0.28 ± 0.29 G2: 0.29 ± 0.22 G3: 0.43 ± 0.42 G4: 0.32 ± 0.21 p=ns</p> <p>Social relationships G1: -0.27 ± 0.21 G2: -0.28 ± 0.18 G3: -0.30 ± 0.19 G4: -0.26 ± 0.16 p=ns</p> <p>Affectual relationships G1: 0.04 ± 0.06 G2: 0.11 ± 0.13 G3: 0.09 ± 0.15 G4: 0.07 ± 0.09 p=ns</p> <p>Sensory responses G1: 0.29 ± 0.17 G2: 0.27 ± 0.16 G3: 0.26 ± 0.17</p>

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		<p>G4: 0.00 ± 0.24</p> <p>Day before challenge Minutes of sleep G1: 631 ± 67.3 G2: 627 ± 76.6 G3: 616.7 ± 48.3 G4: 693 ± 56.4</p> <p>Number of wakings G1: 0.34 ± 1.53 G2: 0.10 ± 0.30 G3: 0.11 ± 0.40 G4: 0.08 ± 0.27</p>	<p>G4: 0.32 ± 0.18 p=ns</p> <p>Language G1: -0.03 ± 0.25 G2: -0.03 ± 0.25 G3: -0.07 ± 0.32 G4: 0.00 ± 0.25 p=ns</p> <p>Day after challenge Minutes of sleep G1: 646 ± 69.1 G2: 641 ± 68.2 G3: 633 ± 70.7 G4: 641 ± 61.3 p=ns</p> <p>Number of wakings G1: 0.20 ± 0.58 G2: 0.03 ± 0.16 G3: 0.17 ± 0.45 G4: 0.05 ± 0.22 p=ns</p>
<p>Navarro et al., 2015⁵¹ RCT</p> <p>G1: "gluten-dairy containing (GD(+)) diet", 6/6 G2: gluten-dairy free (GD(-)) diet, 6/6</p> <p>4 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 6 (6-7) G2: 5.5 (4-7)</p> <p>IQ G1: 55 (52-88) G2: 79 (76-97)</p>	<p>ABC-Irritability G1: 19.77 ± 15.15 G2: 10.50 ± 8.55</p> <p>ABC- Hyperactivity G1: 23.20 ± 11.28 G2: 22.17 ± 7.31</p> <p>Connors Parent Rating Scale-Revised- Cognitive Problems/Inattention G1: 12.17 ± 7.11 G2: 15.83 ± 3.82</p>	<p>EOT ABC-Irritability G1: 16.0 G2: 14.50 G1 vs G2, p= NR</p> <p>ABC-Hyperactivity G1: 26.5 G2: NR</p> <p>Connors Parent Rating Scale-Revised G1: 21 G2: NR</p>
<p>Pusponegoro et al., 2015⁵² RCT</p> <p>G1: Gluten-casein, 38/24 G2: Placebo, 36/26</p> <p>7 days/EOT</p> <p>Moderate RoB</p>	<p>Age, median (range) G1: 5.4 (4.8- 6.7) G2: 5.1 (4.3- 6.1)</p> <p>IQ NR</p>	<p>Pervasive Developmental Disorder Behavior Inventory – Approach Withdrawal problems composite</p> <p>AWPC G1: 56.96 ± 11.72 G2: 57.08 ± 11.46</p> <p>Gastrointestinal</p>	<p>EOT Pervasive Developmental Disorder Behavior Inventory - Approach Withdrawal problems composite</p> <p>AWPC G1: 39.38 ± 2.89 G2: 39.63 ± 3.05 G1 vs G2: p=ns</p>

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		<p>Symptom Severity Index, median G1: 0 G2: 0</p>	<p>Gastrointestinal Symptom Severity Index, median (range) G1: 3 (0-9) G2: 0 (0-7) G1 vs G2: p=ns</p>
<p>Whiteley et al., 2010^{53,746} RCT</p> <p>G1: Gluten and casein-free diet, 38/26 G2: No diet, 34/29</p> <p>24 months/EOT</p> <p>Moderate RoB</p>	<p>Age, months G1: 94.2 [IQR 76.6-118.0] G2: 96.4 [IQR 76.3-120.3]</p> <p>IQ NR</p>	<p>ADOS-Communication G1: 1.13 G2: 1.00</p> <p>ADOS-Social G1: 1.18 G2: 1.22</p> <p>ADOS-Repetitive G1: 0.46 G2: 0.36</p> <p>GARS-Social G1: 6.96 G2: 6.41</p> <p>GARS-Communication G1: 7.23 G2: 7.28</p> <p>GARS-Stereotyped G1: 6.81 G2: 6.76</p> <p>VABS-Communication G1: 66.46 G2: 62.45</p> <p>VABS-Social G1: 64.58 G2: 64.03</p> <p>VABS-Daily Living G1: 59.88 G2: 55.55</p> <p>ADHD-IV scale- Inattention G1: 11.96 G2: 11.21</p>	<p>8 months ADOS-Communication G1: 0.87 G2: 1.07 G1 vs G2: p=ns</p> <p>ADOS-Social G1: 1.09 G2: 1.30 G1 vs G2: p=ns</p> <p>ADOS-Repetitive G1: 0.35 G2: 0.34 G1 vs G2: p=ns</p> <p>GARS-Social (8 mos) G1: 5.88 G2: 6.34</p> <p>GARS- Social (12 mos) G1: 5.38 G2: 6.00 G1 vs G2: p=ns</p> <p>GARS-Communication (8 mos) G1: 6.00 G2: 6.76</p> <p>GARS-Communication (12 mos) G1: 5.74 G2: 5.81 G1 vs G2: p=ns</p> <p>GARS-Stereotyped (8 mos) G1: 5.85 G2: 5.97</p>

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		<p>ADHD-IV scale- Hyperactivity G1: 10.31 G2: 10.79</p>	<p>GARS-Stereotyped (12 mos) G1: 5.35 G2: 5.37 G1 vs G2: p=ns</p> <p>VABS-Communication (8 mos) G1: 66.69 G2: 63.46</p> <p>VABS-Communication (12 mos) G1: 67.38 G2: 64.07 G1 vs G2: p=ns</p> <p>VABS-Social (8 mos) G1: 66.12 G2: 65.39</p> <p>VABS-Social (12 mos) G1: 60.42 G2: 61.21 G1 vs G2: p=ns</p> <p>VABS-Daily Living (8 mos) G1: 62.92 G2: 55.18</p> <p>VABS-Daily Living (12 mos) G1: 63.35 G2: 53.96 G1 vs G2: p=ns</p> <p>ADHD-IV scale-Inattention (8 mos) G1: 9.81 G2: 11.52</p> <p>ADHD-IV scale-Inattention (12 mos) G1: 9.77 G2: 11.11 G1 vs G2: p=ns</p> <p>ADHD-IV scale-Hyperactivity (8 mos) G1: 8.27</p>

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			<p>G2:10.62</p> <p>ADHD-IV scale- Hyperactivity(12 mos) G1: 8.62 G2:10.00 G1 vs G2: p=ns</p>
<p>Knivsberg et al., 2002^{54, 55} RCT</p> <p>G1: Gluten and Casein free diet, 10/10 G2: Normal Diet, 10/10</p> <p>12 months/EOT</p> <p>Moderate ROB</p>	<p>Age (months) G1: 91 (62-120) G2: 86 (59-127)</p> <p>IQ NR</p>	<p>Leiter R-Nonverbal Cognitive Level G1: 81 ± 35.9 G2: 84.6 ± 36.6</p> <p>Parent Questionnaire ND</p> <p>DPBC-Communication and Interaction G1: 3.9 ± 0.9 G2: 4.3 ± 1.3</p> <p>DPBC-Resistance to Communication and Interaction G1: 2.5 1 G2: 2.3 1.7</p> <p>DPBC-Social Interaction and Isolation G1: 7.6 ± 1.7 G2: 7.1 ± 2.8</p> <p>DPBC-Unusual and Bizarre Behavior G1: 4.9 ± 1.5 G2: 4.5 ± 1.6</p> <p>DPBC-Autistic Behavior G1: 12.5 ± 2.2 G2: 11.5 ± 3.9</p>	<p>Leiter R-Nonverbal Cognitive Level G1: 86.7 ± 38.5 G2: 74.3 ± 31.4 G1 vs G2, p=0.004</p> <p>Parent Questionnaire- Attention G1 vs G2, p<0.028</p> <p>Parent Questionnaire- Social and Emotional Factors G1 vs G2, p<0.004</p> <p>Parent Questionnaire- Communicative Factors G1 vs G2, p<0.007</p> <p>Parent Questionnaire- Cognitive Factors G1 vs G2, p<0.019</p> <p>Parent Questionnaire- Sensory/Motor Factors G1 vs G2, p=ns</p> <p>DPBC-Communication and Interaction G1: 6.2 ± 1.1 G2: 4.5 ± 1.6 G1 vs G2, p<0.004</p> <p>DPBC-Resistance to Communication and Interaction G1: 0.2 ± 0.4 G2: 1.9 ± 1.4 G1 vs G2, p<0.004</p>

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			<p>DPBC-Social Interaction and Isolation G1: 3 ± 1.4 G2: 6.2 ± 2.9 G1 vs G2, p<0.003</p> <p>DPBC-Unusual and Bizarre Behavior G1: 2.6 ± 1.7 G2: 4.8 ± 2.6 G1 vs G2, p<0.007</p> <p>DPBC-Autistic Behavior G1: 5.6 ± 2.4 G2: 11.2 ± 5 G1 vs G2, p<0.001</p>
<p>Elder et al., 2006^{56, 57} RCT</p> <p>G1: Gluten and Casein free diet/Regular Diet, 15 G2: Regular Diet/Gluten and Casein free diet, 15</p> <p>12 weeks/EOT</p> <p>Moderate ROB</p>	<p>Age 7.32 ± 4.1 (2-16)</p> <p>IQ NR</p>	<p>CARS-Total Score ND</p> <p>Ecological Communication Orientation Language Sampling Summary ND</p> <p>Behavioral Response Frequencies-Child Initiating ND</p> <p>Behavioral Response Frequencies-Child Responding ND</p> <p>Behavioral Response Frequencies-Intelligible Words ND</p> <p>Verbal Social Exchanges-Verbal Responses G1: 16 ± 27 G2: 16 ± 27</p> <p>Verbal Social Exchanges-Verbal</p>	<p>6 Weeks CARS-Total Score G1: 33.6 ± 8.6 G2: 31.2 ± 8.7 G1 vs G2, p=ns</p> <p>Ecological Communication Orientation Language Sampling Summary G1: 175.8 ± 86.4 G2: 174.4 ± 86 G1 vs G2, p=ns</p> <p>Behavioral Response Frequencies-Child Initiating G1: 9.5 ± 9.6 G2: 7.5 ± 6.1 G1 vs G2, p=ns</p> <p>Behavioral Response Frequencies-Child Responding G1: 27.7 ± 21.8 G2: 14.3 ± 6.5 G1 vs G2, p=ns</p> <p>Behavioral Response Frequencies-Intelligible Words G1: 26.8 ± 35.1</p>

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		<p>Imitation G1: 3.85 \pm 6.9 G2: 3.85 \pm 6.9</p> <p>Lexical Productions G1: 35 \pm 37 G2: 35 \pm 37</p>	<p>G2: 24 \pm 43.5 G1 vs G2, p=ns</p> <p>Verbal Social Exchanges-Verbal Responses G1: 11 \pm 12 G2: 11 \pm 12 G1 vs G2, p=ns</p> <p>Verbal Social Exchanges-Verbal Imitation G1: 1.85 \pm 2.23 G2: 1.85 \pm 2.23 G1 vs G2, p=ns</p> <p>Lexical Productions G1: 32 \pm 33 G2: 32 \pm 33 G1 vs G2, p=ns</p> <p>12 Weeks CARS-Total Score G1: 37.5 \pm 6.6 G2: 33.5 \pm 8.4 G1 vs G2, p=ns Change score G1: 1.2 \pm 6 G2: 2 \pm 7.7</p> <p>Ecological Communication Orientation Language Sampling Summary G1: 111.6 \pm 46.6 G2: 162.9 \pm 108.8 G1 vs G2, p=ns Change score G1: -42.2 \pm 38.1 G2: -4.1 \pm 68</p> <p>Behavioral Response Frequencies-Child Initiating G1: 5.2 \pm 3.2 G2: 10.8 \pm 8.4 G1 vs G2, p=ns Change score G1: -0.6 \pm 4.5 G2: 3.3 \pm 8.4</p>

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			<p>Behavioral Response Frequencies-Child Responding G1: 15 ± 15 G2: 11.9 ± 4.5 G1 vs G2, p=ns Change score G1: -8.4 ± 7 G2: -2.4 ± 7.7</p> <p>Behavioral Response Frequencies-Intelligible Words G1: 12.4 ± 14.2 G2: 30.9 ± 36 G1 vs G2, p=ns Change score G1: -2.6 ± 12.4 G2: 6.9 ± 17</p> <p>Verbal Social Exchanges-Verbal Responses G1: 15 ± 18 G2: 15 ± 18 G1 vs G2, p=ns</p> <p>Verbal Social Exchanges-Verbal Imitation G1: 3.54 ± 7.84 G2: 3.54 ± 7.84 G1 vs G2, p=ns</p> <p>Lexical Productions G1: 37 ± 34 G2: 37 ± 34 G1 vs G2, p=ns</p>
<p>Ghalichi et al., 2016⁵⁸ RCT</p> <p>G1: Gluten free diet, 38/38 G2: Regular diet, 38/38</p> <p>6 weeks/EOT</p> <p>High ROB</p>	<p>Age G1: 7.84 ± 3.55 G2: 8 ± 3.22</p> <p>IQ NR</p>	<p>GARS-Steretyped Behaviors G1: 17.61 ± 6.74 G2: 18.92 ± 5.89</p> <p>GARS-Communication G1: 33.87 ± 8.31 G2: 32.53 ± 9.48</p> <p>GARS-Social Interaction</p>	<p>GARS-Stereotyped Behaviors G1: 14.5 ± 7.92 G2: 19.32 ± 6.27 G1 vs G2, p<0.001</p> <p>GARS-Communication G1: 32.97 ± 9.28 G2: 32.58 ± 9.4 G1 vs G2, p=0.005</p>

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		<p>G1: 19 ± 50 G2: 14 ± 36.8</p> <p>GARS-Total Score G1: 18.14 ± 19.36 G2: 18.99 ± 21.5</p> <p>Rome-III-Stomachache G1: 11 (28.9) G2: 10 (26.3)</p> <p>Rome-III-Bloating G1: 21 (55.3) G2: 18 (47.4)</p> <p>Rome-III-Constipation G1: 19 (50) G2: 14 (36.8)</p> <p>Rome-III-Diarrhea G1: 1 (2.6) G2: 3 (7.9)</p>	<p>GARS-Social Interaction G1: 2 ± 5.3 G2: 18 ± 47.4 G1 vs G2, p=0.66</p> <p>GARS-Total Score G1: 14.91 ± 16.94 G2: 20.72 ± 22.72 G1 vs G2, p=NR</p> <p>Rome-III-Stomachache G1: 7 (18.4) G2: 12 (31.6) G1 vs G2, p=NR</p> <p>Rome-III-Bloating G1: 13 (34.2) G2: 19 (50) G1 vs G2, p=NR</p> <p>Rome-III-Constipation G1: 2 (5.3) G2: 18 (47.4) G1 vs G2, p=NR</p> <p>Rome-III-Diarrhea G1: 1 (2.6) G2: 5 (13.2) G1 vs G2, p=NR</p>
<p>Johnson et al., 2011⁵⁹ RCT</p> <p>G1: Gluten free and Casein free diet, 8/8 G2: Healthy, low sugar diet, 14/14</p> <p>3 months/EOT</p> <p>Moderate ROB</p>	<p>Age (months) G1: 40.13 ± 9.26 G2: 39.5 ± 8.72</p> <p>IQ NR</p>	<p>Mullen Scales of Early Learning-Visual Reception G1: 30.6 ± 11.5 G2: 26.1 ± 10.9</p> <p>Mullen Scales of Early Learning-Fine Motor G1: 28.3 12.8 G2: 27.9 10.8</p> <p>Mullen Scales of Early Learning-Receptive Language G1: 26.1 ± 13.6 G2: 23.5 ± 13.6</p> <p>Mullen Scales of Early Learning-Expressive Language G1: 21 ± 10.2</p>	<p>Mullen Scales of Early Learning-Visual Reception G1: 28.9 ± 11.9 G2: 30.1 ± 10.6 G1 vs G2, p=0.005</p> <p>Mullen Scales of Early Learning-Fine Motor G1: 28 ± 12.1 G2: 30.1 ± 10.3 G1 vs G2, p=ns</p> <p>Mullen Scales of Early Learning-Receptive Language G1: 26.9 ± 11.6 G2: 25 ± 13.5 G1 vs G2, p=NS</p> <p>Mullen Scales of Early</p>

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		G2: 21.5 ± 11.6 CBCL-Total Score G1: 64.3 ± 8.35 G2: 60.2 ± 11 Direct Behavior Observation Measure- Verbal G1: 19 ± 6.37 G2: 16 ± 9.79 Direct Behavior Observation Measure- Attend G1: 28.1 ± 5.46 G2: 24.2 ± 6.68 Direct Behavior Observation Measure- Initiate G1: 2.38 ± 1.92 G2: 3.46 ± 3.28	Learning-Expressive Language G1: 25 ± 10.5 G2: 22.9 ± 12.9 G1 vs G2, p=ns CBCL-Total Score G1: 62.1 ± 4.8 G2: 60.3 ± 9.38 G1 vs G2, p=ns Direct Behavior Observation Measure- Verbal G1: 15.5 ± 8.93 G2: 14.9 ± 9.77 G1 vs G2, p=ns Direct Behavior Observation Measure- Attend G1: 23.4 ± 10.3 G2: 23.3 ± 7.84 G1 vs G2, p=ns Direct Behavior Observation Measure- Initiate G1: 3.5 ± 3.67 G2: 3.58 ± 4.52 G1 vs G2, p=ns

ABC-Aberrant Behavior Checklist; VABS-Vineland Adaptive Behavior Scale; EOT-End of Treatment; AWPC-Approach Withdrawal Problems Composite; ADOS-Autism Diagnostic Observation Schedule; GARS-Gilliam Autism Rating Scale